March 28, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 28, 2018 12:50 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 10 P.M.

(Pages 2297 through 2438)

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March 28, 2018 P.M.

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I N D E X

TESTIMONY

WITNESS	Direct	Cross	Redirect	Recross
CHAD MODRA	2310	2357	2379	

E X H I B I T S

Number		Ident	Rec'd
1680	McDonald Deposition, 07/29/2016 - Exhibit 21 - 7/13/2015 Warning Letter from the FDA regarding the 11/25/2014 Inspection of the C.R. Bard facility in NY and the 11/18/2014-1/5/2015 Inspection of the BPV facility in AZ	2357	
2048	Sullivan Deposition, 09/16/2016 - Exhibit 437 - Document entitled "Failure Investigations/R002 History Review"	2369	2369
2217	Williamson Deposition, 09/07/2016 - Exhibit 105 - Cover page entitled "Attachment 1.14", followed by the 1/23/2015 Memo from Ludwig to Chad Modra Re. "IVC FIlters Retrospective Review", detailing the 2-year review of 939 filter complaints from 1/2013 to 1/2015, with a chart detailing whether the MDR classification changed for any complaints	2365	2366
4327			2310
5483	July 26, 2005 Conference FDA and BPV re Modified Recovery (K050558)	2335	2338
5560	Standard Operating Procedures / Division Operating Procedures -- CQA-STD-R002 Rev 11	2344	2345
5851	TD-04698 Re_Retrospective IVC Filter Review.pdf	2327	2329
5872	FDA Warning Close Out Letter	2333	2334

E X H I B I T S (Continued)

Number		Ident	Rec'd
5874	Bard filter rate information December 2016	2347	2351
5994	TD-04316 Nov. 4, 2015 FDA and Bard Teleconference	2321	2323
5995	TD-04326 Oct. 26, 2015 FDA and Bard Teleconference	2319	2321
6038	Nov. 30, 2015 email chain with FDA re MDR Reporting	2323	
6842			2381
7312			2310

MISCELLANEOUS NOTATIONS

RECESSES

	Page	Line
(Recess at 2:30; resumed at 2:47.)	2368	14

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P R O C E E D I N G S

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 12:50.)

THE COURT: Thank you. Please be seated. 12:00:59

All right. Counsel, making the most of the next ten minutes, let me give you a couple of decisions. I am going to admit the last three pages of document 4327 in light of the *Childs* case and the testimony of Mr. Modra. It's clear to me that the MDR records that are collected from representatives and doctors and others are collected regularly in Bard's business, they are retained in the ordinary course of business. They are relied upon by the company. 12:50:37 12:51:06

All of those factors were found sufficient in *Childs* for information from another source to be deemed part of the business record and, therefore, admissible under 803(6) and I think all of that foundation has been laid, particularly in light of Mr. Modra's more detailed explanation of the process of collecting the information. So I'm going to admit 4327. 12:51:20

With respect to the SIR guidelines -- I've again lost the docket number. 12:51:40

COURTROOM DEPUTY: 7312.

MR. MANKOFF: Just one point of clarification. I thought I heard you state last three pages and I believe it's the last four that are at issue.

THE COURT: That's fine. Whatever those pages are. 12:51:49

7312 I'm going to admit it for purposes of notice and knowledge within the medical community. I think the *Buttice* case and the cases that it cites makes clear that it's an appropriate use of the document. But I'm going to give that instruction that the jury cannot consider it for the truth of the facts and details included in it. But for purposes of establishing notice to, and knowledge of, the medical community and I'll do that when the jury comes back in. Well, unless you want me to wait until the end of Mr. Modra. I'll admit both of those documents and give the limiting instruction.

The purpose for the jury instruction discussion is just to get any additional objections on the record. It's not to argue them because, obviously, we don't have time. Let me put a couple of things on the record from my review last evening that you've already picked up with respect to the instructions.

I added to the punitive damages instruction -- wait a minute. I'm going to get confused here. I added to instruction number 14, which is the -- on page 17. I added the next-to-the-last paragraph on page 17 regarding FDA regulatory action with respect to the G2 filter because it appeared to me that was appropriate under Georgia law and relevant. I also made clear that that isn't controlling. It can still be defective even in the absence of regulatory action.

I have not added what the defendants asked about, the

FDA warning letter. It seems to me that is commenting too much on the evidence in light of Mr. Modra's testimony. The defendants can make the arguments they choose. 12:54:03

I did give although in revised form, the plaintiff requested instruction on the inability of an FDA person to testify so the jury understands why no witnesses have appeared. But I made it clear that both sides are unable to call those witnesses. I revised the superseding cause instruction working off of Mr. Stoller's draft and did a little tweaking of the language, but it's essentially that same idea with some modifications to the language. 12:54:19 12:54:38

I did not include the instructions the plaintiffs requested regarding adulterated and misbranded information. I feel that's too much of a comment on the evidence that has been elicited in this case. And I did not give the requested instruction on the 510(k) process because I think the evidence has been consistent that it's a clearance and not an approval. 12:55:00

I did not give the defendants' failure to warn instruction -- I'm sorry, failure to read the warning instruction and I've expressed the reasons before why I had concerns about that. 12:55:19

And I made other changes but I wanted to put on the record that I did those.

If plaintiff has specific comments or objections you want to get on the record before the instructions are given, 12:55:33

let's do that now but, again, we're not here to argue it, just to make the record. 12:55:36

MR. STOLLER: Your Honor, let me take them in the order that they are in the instructions that you gave to us before the lunch hour. And in particular, we'll start with the first one that you identified which is the addition on the regulatory action in the design defect instruction. We've objected to that. We object to it as we did before. We do think that's a comment on the evidence. 12:55:52

THE COURT: All you need to do is state the objection. 12:56:10

MR. STOLLER: Well, I'm tying it to the other one. In the absence of the limiting instruction we asked for with respect to the 510(k) process, the jury has no basis to understand how the interrelation of those things without that 510(k) process information. 12:56:20

THE COURT: Okay.

MR. STOLLER: And I think there has been some testimony by Bard witnesses about approval in this case and that is another reason why we think that 510(k) process instruction is important. 12:56:31

THE COURT: All right.

MR. STOLLER: In addition to the number of tests that they have put in in bulk in this case.

The next problem, Your Honor, as I see it, is the one 12:56:47

we discussed last night in the instruction by Dr. Amer with respect to comparative fault and particularly the inclusion of the term "usually" in C. 12:56:51

You had asked us to look at some stuff and come back to you on that today, Your Honor. I'm going to direct you to a couple of cases under Georgia law. One is the ***Beach*** decision. ***Beach v. Lipham***, which is 578 S.E. 2d 402 which is the Georgia Supreme Court decision about this instruction and I would -- Your Honor, I'll take that in conjunction with ***Killingsworth*** which I know you have read on the other stuff. 12:57:03 12:57:25

The problem with the term "usually" here, Your Honor, is it's misleading. The jury has no basis to understand when it's required and when it's not required. The ***Beach*** decision doesn't have usually as part of the pattern instruction. It gives -- toward the end, it says what the instruction should be and it says that expert testimony is required. 12:57:39

If you look at that in conjunction with ***Killingsworth***, which talks about why they usually comes into play, ***Killingsworth*** said the standard is so well-known as not to require expert testimony before the jury in matters which juries must be credited with knowing by reason of common knowledge. There's nothing in this case about Dr. Amer's actions that are going to fall within those kind of exceptions. They can understand, hey, we know what he should have done. We think it is improper for that reason. 12:57:57 12:58:15

THE COURT: Okay. 12:58:18

MR. STOLLER: I think we're fine, Your Honor, with the instruction you're giving on number 20 which is the intervening cause instruction. I didn't see what differences are there between my draft and your draft but it reads to me as 12:58:31 consistent with that. I think the problem is the issue we identified both last night and again this morning with -- I'm going to call him Dr. S.

THE COURT: We'll talk about that separately.

MR. STOLLER: And separately the problem of how it 12:58:48 plays out in the verdict form. And I recognize you added some parenthetical language. From our perspective, we think that may make -- actually make things worse. We don't think there should be anything on the verdict form about intervening cause, and maybe there won't be by the time we get through our 12:59:02 directed verdict motions.

Regardless, if there is going to be an intervening cause to go to the jury, we don't think it should be on the jury form. It's going to create a huge problem of them trying to figure out what they are calculating on the different lines. 12:59:13 Candidly, we won't know what they have done.

THE COURT: Is that all of your comments?

MR. STOLLER: Anything else?

MS. LOURIE: The only other comment is what I've already addressed yesterday about that little sentence to add 12:59:24

to the warning. 12:59:27

THE COURT: Which one is it?

MS. LOURIE: It's the failure to warn. It was that sentence about the warning being inadequate if it does not provide a complete disclosure of both the existence of the risk 12:59:38 and the extent of the danger and severity of any potential injury involved.

THE COURT: Right. Okay. That is on the record.

How about from the defense side?

MR. NORTH: Your Honor, the only things we would like 12:59:48 to preserve for the record was our request number four, which the Court just mentioned, about the failure to read the warning and our request number ten about punitive damages and dissimilar conduct. We believe both of those should have been given. 01:00:02

THE COURT: Dissimilar conduct has been added. It's at the end of instruction A at the end of the materials and I added that, by the way, because that's a pattern Georgia jury instruction in a punitive damages case. So the last paragraph in instruction A, which is only going to be given if the jury 01:00:36 decides to award damages, includes that idea.

MR. NORTH: Then we're down to just number four, Your Honor.

THE COURT: Okay.

MR. STOLLER: I'll amend then what I said before, 01:00:48

Your Honor. We missed that in going through it. We don't think it's supported by the evidence and we've made that argument. 01:00:50

THE COURT: Okay.

All right. So we're going to continue -- we need to hold off on our discussion of Dr. S because that's going to take more than a couple of minutes. 01:00:57

MR. O'CONNOR: Your Honor, I have a minor point. In view of your ruling on the one SIR guidelines, we would ask that you also admit then the 2016 SIR which is Exhibit 68 -- 01:01:10

THE COURT: Let's not take that up while we're keeping the jury waiting because that's going to be a discussion. I don't know anything about that guideline. If you want to move it into evidence, you can; but, otherwise, let's wait until after we take the next break. 01:01:25

And we'll talk about Dr. S then as well.

MR. STOLLER: We're going to do that at the next break?

THE COURT: Yes, because I don't want to keep the jury waiting again. 01:01:36

Traci, let's go ahead and bring them in.

You can come up to the witness stand, Mr. Modra.

(Jury enters at 1:03.)

THE COURT: Thank you. Please be seated.

Ladies and gentlemen of the jury, I apologize for 01:03:17

being a couple of minutes over time. 01:03:20

Two matters. I am admitting all of Exhibit 4327. You probably don't remember that number but that's an exhibit on which I had previously not admitted the last four pages. That is now all coming into evidence, so that entire document 01:03:37 will be in evidence.

And also with respect to Exhibit 7312, which are the SIR guidelines, I am going to admit them but with a limiting instruction to you. Those guidelines, under the Rules of Evidence, cannot be considered for the truth of what is said in 01:03:56 the guidelines. So if there's a statement in there, you are not to consider that document as proving the truth of that statement. What you can consider those SIR guidelines for is to establish the notice and the knowledge to the medical community about IVC filters. 01:04:16 So it's being admitted for that limited purpose, knowledge of the medical community, but not for the truth of the matter asserted in the document itself.

All right. You may continue, Mr. North.

(Exhibit Numbers 4327 and 7312 were admitted into evidence.) 01:04:29

MR. NORTH: Thank you, Your Honor.

(CHAD MODRA, a witness herein, was previously duly sworn or affirmed.)

DIRECT EXAMINATION (Continued)

BY MR. NORTH: 01:04:34

Q. Mr. Modra, before the lunch break we were talking about the warning letter that Bard received in July of 2015. Let me ask you this: Did the warning letter in any way address a defect or a claim of defect in the design of the G2 Filter? 01:04:35

A. No. 01:04:54

Q. Did the warning letter address in any way a claim of a defect in the warnings given in the IFU with the G2 filter?

A. No.

Q. Did the warning letter in any way say that the G2 filter was unsafe? 01:05:16

A. No.

Q. Mr. Modra, in the warning letter, was there an issue regarding the missed reporting or claim of missed reporting and event associated with a patient death?

A. There was. 01:05:36

Q. And do you know what happened in that circumstance, what the background was of that alleged misreporting?

A. I do.

Q. Could you tell the members of the jury what that event was that led to the -- what happened that led to the FDA warning letter on that event? 01:05:50

A. The FDA noted that as one of their points of example of where we hadn't filed paperwork properly with them. In the warning letter it said that we had -- it's part of the MDR filing, checked the wrong box and designated something that was 01:06:15

actually related to a patient death as a serious injury or as a malfunction. 01:06:19

And the circumstance behind that, which I did some investigation, understanding of what occurred there, even though they stated that in the warning letter -- 01:06:35

MR. O'CONNOR: Objection, Your Honor. The witness is testifying about an out-of-court hearsay document.

THE COURT: I don't believe he is. Overruled.

BY MR. NORTH:

Q. You may continue. 01:06:50

THE COURT: You need to testify from your knowledge.

THE WITNESS: Yeah. Yeah. I've looked at the documents.

BY MR. NORTH:

Q. Continue, please. 01:06:56

A. As part of our complaint-handling process that I described before, there is a checklist that we go through and it's called the MDR decision and it asks you a series of questions that I noted. We had originally filed this complaint based on limited information. We received the first version of it. It didn't 01:07:15 allege any serious injury so we filed it with the FDA as a malfunction. We had that in our records and we filled out the form required by FDA and we sent it to them as malfunction.

Sometime later, we got more information from the doctor and it included notification that the patient had died. 01:07:34

So we refilled out the information and what we had failed to do even though we wrote it in the record itself where the narrative matched what information we got, we said that it should be reported as a patient death on a new form except we said that in our checklist. We reported it as a patient death on a supplemental MDR form. So we sent back another form to FDA saying that there was a patient death but our records, internal records, which are very important, didn't match what we told the FDA. 01:07:40 01:08:01

So we came back and we had reported it as a patient death. But our internal records didn't match it and the investigator that was going through those records determined that it's important to have what they have as filed under a certain category matched what we had justified or answered the questions to. 01:08:19 01:08:37

So they had cited that as one of the examples that she found in all of the records that she looked through as not having complete documentation.

BY MR. NORTH:

Q. You said all of the records she looked through. Was the FDA inspector provided access during those inspections to all of Bard Peripheral Vascular's complaint files? 01:08:50

A. She asked, which is the common practice these days, for a download on a CD so we took the entire database across the time period. I can't remember what time period she asked for but 01:09:09

she asked for it to download into a CD on an Excel table so she could double-check and look at every bit of the records. 01:09:13

Q. So with the one you were just describing regarding a death of a patient, was that correctly reported to the FDA itself in the supplemental report? 01:09:30

A. It was and it was actually -- even though it was cited in the nonconformance as an example, we had actually found that discrepancy during a routine quality check earlier and put a note to the file to indicate that we had had that discrepancy. And she still cited that as one of the examples. 01:09:51

Q. Does the FDA have regulations about complaint-handling systems?

A. About having to report MDRs of certain types, yes, and that we must maintain files, complete files, and conduct investigations on all events. 01:10:09

Q. Are those regulations specific to IVC filters?

A. No. They are written universally. No matter whether you have a complicated product or whether you have a simple syringe barrel or whatever the product may be, those apply universally.

Q. Has it been your experience, as a quality professional in the medical device industry, that the FDA has on occasion clarified its positions on what events should be filed with the agency? 01:10:29

A. A number of times. They usually do it through a draft guidance that they will publish or a guidance document. They 01:10:47

will do that periodically and it's -- I mean, my view on it, it's because those regulations are written with such a broad mind, broad product base in mind, they have to issue these clarifications because there is, unfortunately, a lot of barrier head not when it comes to serious injury, when it comes to patient death of course. But whether it comes to malfunction and whether or not to report it, they issue guidances using examples of devices and situations that would be reportable or not reportable. So usually it's in a guidance. 01:10:52 01:11:10 01:11:29

Q. Does the agency on occasion have meetings with the industry to discuss its expectations as to complaint-reporting standards?

A. Yeah. There's symposia, industry meetings that we try to go to. There's a good group in Orange County, regulatory group, that we try to attend because they have days at the FDA office so you can go there and kind of hear them speak directly to a lot of questions. So it's important to be part of those things to hear directly what is their latest thinking on the way something should be reported or how they are ruling on product regulation. 01:11:42 01:12:02

Q. Over the years, have you seen the FDA's interpretation as they applied it to medical device manufacturers like the ones you worked for evolve or change?

A. I have. There's -- an example I can think of is there's 01:12:24

the ability to summary report so sometimes when they understand a product has been out on the market for a long time and they understand the nature of the risks and the benefits of a device. The same types of events will happen, the same experience will happen. When they fully understand those things, you're allowed to have summary reporting where you still report all of those records but you send them in in a quarter, once a quarter. 01:12:31 01:12:44

So they have changed those rules over the years. They have changed how they interpret several of the other reporting rules, still within the regulation but the kinds of things they want you to report. 01:12:59

Q. What are some of the challenges you face as a quality professional with deciding how to classify adverse events in a report and whether to report that to the FDA? 01:13:19

A. Like I said, it's pretty straightforward. Of course when it comes to a serious injury, those are -- no. I mean, those are things that you know are reportable so that's not really a question.

It's really the malfunction of whether or not they want it reported, something that may or could potentially lead to harm or maybe has never led to harm before but they still want it reported. That is the gray area that they have provided more and more guidances on and it generally has trended to have more reporting. I think they have -- over last 01:13:39 01:14:05

few years I have been to some symposia where they mentioned having greater ability to trend it themselves so they are able to handle more data. It's not so much of a paper system. For instance, another example would be a couple of years ago we had to go to electronic MDR reporting so everyone is required to electronically submit this unless you have -- just completely don't have the ability to do it. 01:14:08 01:14:21

So by doing that, they have it automatically entered in electronically. They can do tracking and trending as well.

Q. Now, you mentioned the death that was recorded differently in the internal copy. Was one of the other issues cited by the FDA in the warning letter, did it concern complaint investigation processes regarding component suppliers? 01:14:43

A. It did.

Q. And what device would that have been involving component suppliers? 01:15:04

A. I can't remember.

Q. Do you know if the Denali filter uses components manufactured by other companies?

A. Yes. It's manufactured by a supplier. 01:15:22

Q. Do you know whether the G2 involved any components like the Denali does by other suppliers?

A. It's a different manufacturing process.

Q. Let's pull up Exhibit 5995. If we could look at the second page, please. 01:15:55

Mr. Modra, following the FDA warning letter, the receipt of that, did the company have a number of conferences with the FDA? 01:16:01

A. We did.

Q. And what were the purposes of those conferences? 01:16:12

A. Well, the data -- I had said earlier the warning letter you have to respond very quickly. The day that we sent in the response, we wanted to make sure that we contacted FDA because one of our responses or part of our responses are looking at all the records. You know, we wanted to be thorough, like I said before, about understanding the system and we had contacted them that day that we sent in the response in order to try and have a discussion with them, because it seemed both in the warning letter they were telling us their expectations had changed on what to file and we were interpreting what 01:16:31 01:16:53 records to file as MDRs were different than, obviously, they were expecting. So before we went back and took a look at all of the records and made sure we had all of them refiled appropriately, we wanted to make sure that our draft estimate of the expectations was consistent with them because you don't want to do that work and interpret it incorrectly. 01:17:14

So we were fortunate enough to be given a series of teleconferences with them where we presented information and they gave us their answers, this is exactly how we wanted to file or not. 01:17:37

Q. We saw earlier the exhibit that were the MDR regarding guidelines and revision five indicated it was revised after consultation with the FDA. 01:17:38

Was that particular guideline for MDR reporting, was that discussed with the FDA during these teleconferences? 01:17:54

A. In the first teleconference that we got, it was great because there's a segment of the FDA that makes the decisions. There's a head person that -- and her staff makes the decisions on whether things are reportable or not, MDR reportable.

So we were fortunate enough to get a teleconference with her and some of that staff and we shared with them a draft version of the MDR reporting guidelines, the index. We sent that to them and they gave us feedback. In my experience, it's fairly rare to get that candid experience or that candid of feedback. They liked the matrix. They liked what they saw, the draft. So we said, "Well, that's great. Can we share" -- because we had done the same thing with all of our other product lines. 01:18:13 01:18:38

MR. O'CONNOR: Objection, Your Honor, to his testimony about how the FDA felt about things or what they said. It's hearsay. 01:18:51

THE COURT: Please ask the question in that way, Mr. North.

BY MR. NORTH:

Q. Let me ask you this: Turning to Exhibit 5995, does this 01:19:02

reflect minutes of an October 26, 2015, conference with the FDA? 01:19:05

A. It does.

Q. And did you participate in that conference?

A. I did and I wrote the minutes. 01:19:14

Q. And who participated from the FDA in that teleconference?

A. Ms. Sharon Kapsch, who is the Consumer Safety Officer; Michelle Rios; Linda Hoffman; Anna Alexander; and Lieutenant Commander Catherine Beer.

Q. And are any of those the person that you referenced that was sort of in charge of determining whether things are reportable? 01:19:35

A. Yes. Ms. Sharon Kapsch.

Q. And who prepared these minutes?

A. I did. 01:19:49

Q. And were they prepared soon after the meeting that took place?

A. Yes. Immediately after, within a day or two at the most.

Q. Were they prepared and kept in the course of your regular business activity? 01:20:04

A. Yes. Whenever we contact FDA or had that kind of discussion, we keep meeting minutes just for our record.

Q. And is that a regular practice of yours, to create minutes such as this after a teleconference with the FDA?

A. Yes. 01:20:19

Q. Were these minutes ever shared with the FDA? 01:20:21
A. I believe they were. We sent them an email kind of confirming to make sure that they agreed with what we had said and what we had concluded in the discussion.
MR. NORTH: Your Honor, at this time we would tender 5995. 01:20:34
MR. O'CONNOR: Objection, hearsay within hearsay. I suppose we can admit subject to the agreement we've had.
THE COURT: All right. We'll admit 5995 subject to the parties conferring about hearsay within hearsay. 01:20:48
MR. NORTH: Could we look now at 5994. Going to the second page, please.
(Exhibit Number 5995 was admitted into evidence.)
BY MR. NORTH:
Q. Does this 5994 contain the meeting minutes of a second telephone conference with the FDA? 01:21:08
A. It does.
Q. And what was the date of this conference?
A. The fourth of November, 2015.
Q. And why did Bard and the FDA have another meeting to discuss the MDR reporting guidelines? 01:21:29
A. Because the first meeting was related to filters specifically and the content of the reportability guidelines or matrix that we had developed. We wanted to gain similar agreement on all the other product lines that we had 01:21:47

responsibility for because, again, when you make -- you don't just make a correction to one thing. You look across everything else. 01:21:50

So we developed similar very thick guidelines across all the other product lines. 01:22:02

Q. And did Sharon Kapsch, the person who supervises making reportability determinations at the FDA, did she also participate in this teleconference?

A. She did, and they granted us half an hour and they actually -- because though the half an hour was up and their conference room was being used, they allowed to us call back again a second time and spend more time with them when they moved conference rooms, which I had never experienced that before. 01:22:17

Q. Did you attend that meeting? 01:22:35

A. Yes.

Q. And did you prepare the minutes that are now marked as 5994?

A. I did.

Q. And, again, were these made at or near the time that the conference occurred? 01:22:41

A. Yes, they were.

Q. And are these minutes kept as a regular part of Bard's business files?

A. Yes. 01:22:57

Q. And was that a regular practice of yours, to make such a document? 01:22:57

A. It was.

MR. NORTH: Your Honor, at this time we would tender 5994. 01:23:02

MR. O'CONNOR: Same objection. Same agreement.

THE COURT: All right. This document is admitted subject to the parties' further review for hearsay within hearsay.

(Exhibit Number 5994 was admitted into evidence.) 01:23:14

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q. If we could turn to 6038, please. Do you recognize 6038?

A. I do.

MR. NORTH: If we could look at the second page. 01:23:38

Q. Tell us what that is, please.

A. It's an email chain between our clinical director and Ms. Sharon Kapsch clarifying the last few points from the second meeting.

Q. And who wrote this email for BPV? 01:23:54

A. Dr. Bill Altonaga.

Q. And had he participated in those telephone conversations?

A. He had.

Q. And were you copied on his email?

A. Yes, I was. 01:24:06

Q. And what was the general purpose of his email? 01:24:09

A. We had -- after the --

MR. O'CONNOR: Objection, Your Honor. This is not admitted yet and the witness is testifying from this email.

THE COURT: The question is what was the purpose, not the content. 01:24:21

MR. O'CONNOR: All right. Thank you.

THE WITNESS: After the second meeting, Dr. Altonaga wanted to clarify a few extra things because when we had gone through the second meeting and -- some of the devices are similar in that they are implanted into the body or they are used in a certain way. It seemed like the -- what the FDA was telling us for reportability was different than what we had interpreted in the past. In fact, it was that the records weren't really reportable. 01:24:37 01:24:55

So in order to confirm that and not just make that assumption, he sent them an email asking that question that if that is correct for these other devices, is it also true for IVC filters.

So those are the clarifying points he wanted to make. 01:25:09

BY MR. NORTH:

Q. And without giving us hearsay and telling us what the FDA responded, did the FDA provide a response to Dr. Altonaga's questions?

A. They responded to him, correct. 01:25:23

Q. And did their response assist the company in going forward with the application of the guidelines? 01:25:25

A. Yes.

Q. Now, following the receipt of the warning letter and these discussions with the FDA, did the company conduct a retrospective review of older complaint files? 01:25:39

A. We did.

Q. Explain to the jury what a retrospective review is.

A. When FDA cites a nonconformance and they say in this instance the records were deficient in some manner, it's prudent to not just correct whatever records that they identify but, again, to go back for a period of time to ensure that all of those other records have that additional information. 01:26:00

And then the FDA had noted a couple of places like patient weight, height, age, other -- other things that needed to be added to those records. So we went back and reviewed all the records to try and obtain that additional information. 01:26:21

Q. Now, did one of the topics in the FDA warning letter concern whether reports were characterized as a malfunction or a serious injury? 01:26:45

A. They did.

Q. And did the company look back over reports as part of the retrospective review to reassess the -- whether they had been characterized as malfunctions or serious injuries?

A. We did. 01:27:02

Q. Let me ask you this: Were all of the complaints cited by the FDA with regard to how they were characterized, were all of those actually reported to the FDA? 01:27:04

A. Yes. They were all reported as MDRs. It was -- their point of nonconformance was about whether it was classified as an MDR versus a serious injury which are all reportable anyway. 01:27:21

Q. But all of those reports, regardless of how characterized, would have been reported and made a part of the MAUDE database?

A. Yes. Yes. They were reported. They are in there. It takes a little bit to get there but they are reported. 01:27:39

Q. Did any changes Bard made in whether it categorized reports to the FDA as a malfunction as opposed to a serious injury, did any of those changes affect the rates that Bard's internal calculations and trending demonstrated?

A. No. Because when you're doing the trending, I mentioned that code before, the code which really summarizes the event, what went wrong. We trend on the codes and you can have multiple codes for every event. 01:28:19

So whether you report it or not, that's interesting but it's all about the event code that you're trending on. So every one of the complaint records has a code or multiple codes. So it's independent of whether or not it's reported as an MDR. 01:28:39

Q. Do you trend all complaints even if they are not reported?

A. Yes. You have to. I mean, you can't just exclude things 01:29:00

that aren't reportable. It wouldn't give you the whole picture. 01:29:03

Q. Now, you're talking about these FDA codes, does the FDA have a code for migration for a filter?

A. Yeah. I can't remember the code. 01:29:17

Q. But does it have one?

A. Yes.

Q. Does it have one for fracture?

A. Yes.

Q. Is that called detachment of limb or something like that? 01:29:24

A. Yeah. Detached component I think.

Q. Does it have a code for perforation or penetration?

A. Yes.

Q. Is there a separate code for tilt?

A. Yes. 01:29:41

Q. And are there additional codes for complications that might be associated with IVC filters?

A. Yeah. There's many codes.

MR. NORTH: If we could bring up 5851, please.

BY MR. NORTH: 01:30:06

Q. Do you recognize 5851?

A. I do.

Q. And what is that, sir?

A. It's the re-retrospective review of the BPV filter complaints. 01:30:20

Q. And was this the retrospective review we were just discussing a few minutes ago? 01:30:22

A. It's one of them, correct.

Q. It says that the originator was -- originators were Judy Ludwig and Bryan Vogel. Do you know who those two individuals are? 01:30:34

A. Yes. I do.

Q. And who are they?

A. They are employed in the Field Assurance or Complaint Handling Department at BPV. 01:30:43

Q. And did they work under your supervision while you were there as the vice president?

A. Yes, they did.

MR. NORTH: If we could turn to the next page.

BY MR. NORTH: 01:31:05

Q. Was this document prepared by Ms. Ludwig and Mr. Vogel at or near the time that this analysis was conducted?

A. Yes.

Q. And was this record of that analysis kept in the course of Bard's regular business activity? 01:31:19

A. Correct, yes.

Q. And was making a record of such analyses a regular practice of the company at that time?

A. Yes, it's important to document, you know, decisions and reviews. 01:31:32

MR. NORTH: Your Honor, at this time we would tender 5851. 01:31:38

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit Number 5851 was admitted into evidence.) 01:31:43

MR. NORTH: If we could display the document, Your Honor.

THE COURT: You may.

BY MR. NORTH:

Q. Does this document discuss in a retrospective review of 228 complaint records? 01:32:02

A. Yes, it does.

Q. And was the purpose of this to reanalyze whether these complaints should have been characterized as a malfunction or -- 01:32:34

MR. O'CONNOR: Objection, leading.

THE COURT: Sustained.

BY MR. NORTH:

Q. What was the purpose of this particular retrospective review? 01:32:41

A. Well, after we had had that discussion with FDA, what we thought was going to be their position on fileable or recordable -- I'm sorry, reportable MDRs was actually overreaching. It was conservative. So they told us during the meeting that we had -- we were going to report more than they 01:33:03

really expected us to. 01:33:08

MR. O'CONNOR: Objection, hearsay. They took what the FDA told them in a meeting.

THE COURT: Sustained.

BY MR. NORTH: 01:33:14

Q. Let me ask it this way, Mr. Modra. During your meetings were there discussions to clarify what the FDA's expectations were with how complaints could be characterized?

A. Yes.

Q. Based on the company's understanding of the FDA's expectations, was this retrospective review then conducted? 01:33:29

A. It was.

Q. And if we could look at the next paragraph.

What were the results of this retrospective review?

A. When we had taken another look back after getting clarification from FDA, we really should not have reported serious injury 93 percent of the ones that we had. So as it stated there, it was downgraded to malfunctions post that FDA meeting that we had with them. 01:33:52

Q. So did Bard essentially, for lack of a better word, overreact after the warning letter and become overly conservative in its reporting? 01:34:22

MR. O'CONNOR: Objection. Irrelevant and calls for an opinion of this witness, Your Honor.

THE COURT: Overruled on those grounds. 01:34:38

THE WITNESS: Whenever you have an FDA warning letter, it's important to take an extra measure of reaction and we deemed it appropriate to do that at that time. And that's why it was important for us to get clarification from FDA that that is really at the level at which they wanted us to report those or was it something less. 01:34:43 01:35:01

So, yeah, we may have overreacted but I think it was prudent to do that at the time.

BY MR. NORTH:

Q. Did the warning letter discuss a handful of complaints that were not actually sent to the FDA? 01:35:21

A. I believe it did.

Q. Did those complaints involve delivery system complaints?

A. They did.

Q. And what filters did those concern? 01:35:37

A. Denali.

Q. Did they concern the G2 filter at all?

A. Not to my recollection, no.

Q. Did any of those particular complaints concern Denali complaints, concern fracture, migration, perforation, or tilt? 01:35:56

A. Could you repeat the question?

Q. Did any of those delivery system complaints involving the Denali filter concern fracture, migration, perforation or tilt of the filter?

MR. O'CONNOR: Object to the question about the 01:36:19

Denali, not relevant. 01:36:20

THE COURT: Is this within Section 3 of the warning letter?

MR. NORTH: Yes, Your Honor.

THE COURT: Overruled. 01:36:25

THE WITNESS: They didn't because those would have already been reported. If it involves any of those failure modes, those are being reported. Those are the ones that I said are the more easier ones to understand. Those get reported. It's the other ones that are delivery system related 01:36:45 where the question was, are these reportable or not, because if they -- they didn't result in something to the filter, we had -- we determined it not to be reportable and that's where the FDA landed as well, reportable as a malfunctions.

BY MR. NORTH: 01:37:11

Q. After FDA asked Bard to report those particular Denali complaints, what did the company do?

A. We reported them.

Q. And what impact, if any, did Bard's decision not to report those complaints initially have on the company's internal 01:37:28 trending and determination of rates for fracture, migration, perforation, or tilt of the G2 filter?

A. Nothing because those are were still being reported. All of those other failure modes were still being reported. There wasn't really any change to any of that. So it had no effect 01:37:49

on it. 01:37:52

Q. After receipt of the warning letter, did Bard Peripheral Vascular take that seriously?

A. Yes.

Q. And how much time did you personally spend in the weeks and months after the receipt of the warning letter working to address the questions raised? 01:38:20

A. Most every waking moment. 90 percent of my time was spent on that.

Q. Did Bard ultimately satisfactorily respond to FDA's concerns from the warning letter? 01:38:40

A. Yes.

Q. What in your industry or in the regulatory world with the FDA is a warning letter close-out letter?

A. After a series of follow-up visits from FDA unannounced, still they come back to verify that you did what you said you were going to do, that you did that and more and that you've satisfactorily done the things that you said you were going to do. So they send you a close-out letter saying that the warning letter is closed. 01:38:59 01:39:23

MR. NORTH: Could we look at Exhibit 5872?

BY MR. NORTH:

Q. Do you recognize this particular letter?

A. I do.

Q. This is addressed to Mr. Tim Ring, isn't it? 01:39:43

A. It is.
Q. If we could look at the second page. Is it copied to Steve Williamson?
A. It.
Q. And who is Steve Williamson? 01:39:56
A. He's the president of BPV or Bard Peripheral Vascular.
Q. And were you made aware of the receipt of this letter once it came in?
A. Immediately.
Q. And once received from the FDA, was this letter kept in the course of the regularly conducted business of Bard? 01:40:10
A. Yes.
Q. And is it the regular practice of the company to retain official correspondence like this from the Food and Drug Administration? 01:40:22
A. Yes.

MR. NORTH: Your Honor, at this time we would tender Exhibit 5872 into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted. 01:40:32

(Exhibit Number 5872 was admitted into evidence.)

MR. NORTH: Could we display this?

THE COURT: You may.

BY MR. NORTH:
Q. Looking at the first paragraph, Mr. Modra, can you tell 01:40:39

the jury what the FDA said in this letter? 01:40:44

A. Do you want me to read it?

Q. Yes. Just read it.

A. (Reading) The Food and Drug Administration has completed an evaluation of your corrective actions in response to our 01:40:54
warning letter, warning letter 27-15 dated 7-13-2015. Based on our evaluation, it appears that you have addressed the violations contained in this warning letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections. 01:41:16

Q. After the closure letter was received here, has the FDA identified any other alleged violations that might concern IVC filters?

A. No.

Q. And at any time through this entire process, has the FDA 01:41:37
issued any warning letter that questioned the design or the warnings of the G2 filter?

A. No.

Q. Let's talk more about tracking, trending and rates, Mr. Modra. Does Bard have a specific policy or procedure 01:42:22
concerning complete trending or tracking?

A. We do.

MR. NORTH: If we could show Exhibit 5483, please.

BY MR. NORTH:

Q. Do you recognize this? 01:42:39

A. Yes. 01:42:41
Q. What is this?
A. This is the standard operating procedure in the quality area that relates to the complaint trending and what to do, how to do it. 01:42:52
Q. Is this representative of the types of procedures and trending that the company does?
A. This and --
MR. O'CONNOR: Objection, Your Honor. Lack of foundation and irrelevant. If you look at the top of this 01:43:08 document, this is for a whole different FDA process. It's for a PMA process, not for a 510(k).
THE COURT: It hasn't been offered in evidence yet so I don't think that question he's just asked was objectionable. You can certainly object if it's moved into evidence. 01:43:24
BY MR. NORTH:
Q. Is this related to PMA specific products?
A. No.
Q. What does that mean when it says PMA related?
A. The designation of that on a document means that it is 01:43:36 related to PMA products. It's also related to all products because it's important to have that designation at the top because in our old documentation system, you have to have an annual report for a PMA-type product. You have to send that in. So in order to sort documents within our system, you had 01:43:53

to have something that designated it as PMA potentially related. 01:43:57

So we used to sort on that title. It means that's related to all products as well as PMAs.

Q. And you're aware that the IVC filter line is -- are 510(k) products? 01:44:09

A. I'm aware of that.

Q. So this would still be applicable to them?

A. That's correct.

Q. Is this a regular policy or procedure created by the Quality Department at Bard? 01:44:26

A. Yes, it is.

Q. Is it kept in the course of the company's regularly conducted activity?

A. Yes. 01:44:36

Q. And is it a regular practice of the company to maintain policies and procedures such as this?

A. Yes.

Q. And would this policy and procedure have been applied to trending and tracking for IVC filters? 01:44:48

A. Yes, as well as other products.

MR. NORTH: Your Honor, at this time we would tender Exhibit 5483 into evidence.

MR. O'CONNOR: Objection on foundation. Which part of this is applicable to 510(k) process and until then, it's 01:45:02

not relevant, Your Honor. 01:45:06

THE COURT: Overruled. 5483 is admitted.

(Exhibit Number 5483 was admitted into evidence.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes. 01:45:15

MR. NORTH: And if we could go to page two, please.

BY MR. NORTH:

Q. Under F, does this talk about the types of complaint trending that will be monitored by the Field Assurance department? 01:45:42

A. It does.

Q. Are there daily reports?

A. There are.

Q. And what is reported daily under number one?

A. The number of complaints created, closed, MDRs filed and those numbers are being used to predict the month-end results. 01:45:57

Q. Okay. If we could look at number two, is there a weekly report also?

A. There is.

Q. When it says the FDA Device Code of complaints, would that be the type of complication such as migration, fracture or whatever? 01:46:15

A. Yes. It's all the codes that we put in and on all the complaint files.

Q. So would this weekly report indicate to the company how 01:46:29

many reports of fractured IVC filters the company had received in a given week if any? 01:46:32

A. It would.

Q. Would it provide a report of how many fractures -- migrations of a filter, if any, the company had received in a given week? 01:46:47

A. It would.

Q. Let's look at number three. What is QMR?

A. It's an acronym for the Quality Management Report which is a thick report that includes all the tracking, trending by codes, by product, by date. 01:47:04

Q. And let's look at number four. Explain to us what early warning is.

A. We have -- we developed a number of years ago -- actually, while I was at the Salt Lake City plant -- a statistical method for comparing the current reported numbers of events and previous versions. So it wasn't just a visual look at a graph where you can see a rate going down or going up. But it had some statistical analysis to it that it compares current versus three-month, six-month and 12-month performance ago. So by doing that, it highlights it each time you run the program. So you can see where the tracking and trending actually is occurring. 01:47:27 01:47:53

Q. Let's look at the section of that page that talks about rates. And what is the policy that the company follows suggest 01:48:16

you do as far as tracking and trending with regard to rates? 01:48:22
A. It says month to month and then current month as compared against the average from last year.
Q. Does that mean that the company updates its determination of complication rates with the product each month? 01:48:36
A. We update the results of each complication rate each month, correct.
Q. Let's look at number eight on that page, device codes, and, again, are those the complication types that we talked about earlier? 01:48:59
A. Those are.
Q. And are those monitored for signs of trend?
A. They are.
Q. For example, hypothetically with a Recovery filter, if there were complaints coming in of perforation, would the company then monitor that for a trend in those complaints? 01:49:13
A. We would.
Q. And then let's look down at number 10, risk management evaluation. Explain what this is and what that involves.
A. Well, across all the product lines we take the top five product complaints and then we compare those on a rolling average to the previous year and then we evaluate the top three failure modes of those to see what are the primary causes of that rate of the product line. 01:49:38
So it goes from just the product and drills down into 01:49:55

more specifics, what are causing those complaint trends. 01:49:59

Q. Are the complaints sorted or identified by these FDA device codes? Are they kept in a database at the company?

A. They are.

Q. And are you able to run reports at any time that provide you with rates for -- under these various FDA device codes? 01:50:18

A. We are. The database only contains the complaint record and the codes. It wouldn't report the rate itself. That's merged with the internal sales data.

Q. But you're able to lift from -- are you able to lift from the database the number of types of complaints with each device? 01:50:41

A. Yes. For each code, for each device.

Q. And then does the company have current sales data on hand at any time as to a particular product? 01:50:57

A. We do.

Q. Then does your department calculate complication rates based upon the number of events recorded with the device code divided by the number of sales?

A. Yes. 01:51:14

Q. Let me ask you a minute about the DFMEA again. Again what is the purpose of a DFMEA?

A. The DFMEA is a tool, an organizational tool, not unique to us but for estimating the harm of a particular failure mode.

So when you develop a product, you use this FMEA tool 01:51:48

and you get a group of people together and you brainstorm what things could go wrong with the device and you list all of them out and then you assign a severity ranking to those. You use -- we have a -- we have clinical input on these and they assign a number to it. And then you estimate, from any number of sources, how frequent you think that that particular level of safety failure is going to occur. And then you use that tool to really sort out which things are highest risk and the lowest risk. And then that is a tangible way to apply more testing to do additional research, to put a warning in your labeling, any number of ways to mitigate that risk. 01:51:54 01:52:08 01:52:36

So it's not just a guess. It's more tangible than that.

Q. What is a threshold expected failure part as part of a DFMEA? 01:52:57

A. We, as I mentioned, we assign estimated occurrence ratings for each one of the types of the failures of the device. So we use that later on and once the device has been released to the market, we have the ability to then compare what the rate is of that failure in the field or what is at least reported to us compared to where we estimated it originally and see if there's -- if we were on target, if there's something additional we need to do to mitigate the risk. 01:53:15

Q. And what is the purpose of the threshold of these expected failure rates? 01:53:38

A. We have like an early warning system or early trigger that when you set these rates at a certain value or rate, it's good to have them not too high and not too low because if you have them too high, it won't really trigger you to do a further evaluation. If you have them too low, then you investigate everything and it may be noise. So by setting that rate, it's good to have that feedback to compare it to that so we can get an idea is this performing the way we think it is? Is there something else we have to investigate? 01:53:39 01:53:58

Q. For a second generation product, what is your experience as to what the basis of the threshold rates become? 01:54:22

A. The previous generation is important but you also have to take into account is it going to be used exactly the same way? Does it have the same indications for use? Will the same clinical population be using it? You have to factor in other things and understand the total picture but the basis primarily might be the previous generation. 01:54:42

Q. What type of investigation activities are triggered under Bard's quality estoppel if a threshold in a DFMEA is exceeded?

A. If the threshold is exceeded, we conduct a deeper investigation. We have each of the complaints that has an investigation in it for that particular event. But when a threshold is triggered, we start looking additionally across multiple lots. We might look at a time period. We'll look deeper into trends and other data that we have for similar 01:55:02 01:55:23

devices. So it's sort of like a yellow light. Go look at this and find out is there something going on here. 01:55:26

Q. If threshold rate or if a rate exceeds a threshold set by a DFMEA, does that automatically make the product unacceptable to sell? 01:55:44

A. No.

Q. Does it trigger a need under the policy for product remedial actions?

A. It doesn't.

Q. Does Bard have a policy concerning product remedial actions? 01:55:55

A. We do.

Q. Let's look if we could at Exhibit 5560. Can you identify what this is for the record, please.

A. It's CQA-STD-R002, the policy for remedial actions. 01:56:14

Q. And this is dated what?

A. January 15, 2007.

Q. Is there still a -- is this policy sometimes referred to as an R002 policy?

A. Yeah, that's typically what it's referred to as. 01:56:38

Q. And is there still the R002 policy in effect today at Bard?

A. Yes.

Q. And are you familiar with this policy?

A. Very. 01:56:49

Q. Is this policy maintained by the company as part of its regularly conducted business activity? 01:56:53

A. It is.

Q. Is it a regular practice of the company to maintain that policy? 01:57:03

A. It is.

MR. NORTH: Your Honor, at this time we would tender Exhibit 5560.

MR. O'CONNOR: No objection.

THE COURT: Admitted. 01:57:10

(Exhibit Number 5560 was admitted into evidence.)

MR. NORTH: If we could display this to the jury, Your Honor.

THE COURT: You may.

BY MR. NORTH: 01:57:15

Q. What is the purpose of this policy, Mr. Modra?

A. It's to provide a standard for the development and implementation of a remedial action plan which is a determination about a product, whether it needs to be recalled from the field or if there's additional communication, and to 01:57:29 establish a process for the review and approval that of that plan.

Q. How does Bard decide whether remedial action must be taken?

A. You have to conduct an investigation first and then it's 01:57:44

paired with a clinical severity and the estimated rate and there's a chart later on that determines what levels of things you are to do. 01:57:48

MR. NORTH: Let's look at page 11 if we could, please. 01:58:04

BY MR. NORTH:

Q. What is this matrix?

A. The post-market risk assessment matrix.

Q. And what is this used for?

A. This matches the estimated level of severity along the bottom of an issue and the estimated occurrence rate along the side and you find the box and it tells you what things you need to do next. 01:58:18

Q. Is this matrix analysis applied to all products at Bard Peripheral Vascular? 01:58:43

A. Yes, all products.

Q. And is the severest level intolerable?

A. That's the highest risk matrix index, yes, intolerable.

Q. And what does that generally mean if the risk matrix is found to be intolerable? 01:59:07

A. That means you have to take immediate action.

Q. Over the course of your seven years, did Bard and its Quality Department under your supervision continually monitor the complaint rates with regard to the G2 filter?

A. Yes. 01:59:27

Q. And did you specifically track specific complications with the G2 filter that had been reported such as migration, fracture, perforation, tilt? 01:59:29

A. Yes.

Q. During all that time at Bard Peripheral Vascular, to your knowledge, did the company ever determine that the G2 filter under this risk assessment matrix was unsafe? 01:59:45

A. No.

Q. Did the company ever determine under its internal procedures as outlined by this risk matrix that the G2 filter should be recalled? 02:00:03

A. No.

Q. Now, as I recall, you said you still maintain an office out at Bard Peripheral Vascular?

A. I do. 02:00:37

Q. And do you still have contacts with the people that formerly worked under your supervision in the Quality Department?

A. I do.

Q. On a regular basis? 02:00:44

A. Pretty frequently, yes.

Q. If we could pull up what's been marked as 5874. Are you familiar with this document?

MR. NORTH: Can we enlarge this a little bit for those of us that need the help? 02:01:21

THE WITNESS: The question, am I familiar with it? 02:01:25

Yes.

BY MR. NORTH:

Q. Have you seen this before?

A. I have. 02:01:30

Q. And do you know what this is?

A. It's a reporting of the reported rates for each of these complications across the different generations of filters.

Q. And what does this report reflect, complication reports through what date? 02:01:51

A. Through December 16.

Q. And as you told us earlier, how would you determine -- where would you find the number of complications to prepare a document like this?

A. We would take them from the TrackWise database or the complaint handling database. 02:02:15

Q. And how would you determine which complaints are fracture versus migration? Does the FDA Device Code come into play there?

A. From the code. I mean, that's why -- that's the good thing about having the codes. You can sort them just by the code. 02:02:30

Q. And then where do you obtain the sales numbers?

A. From internal data. We have a sales enterprise system database that has those numbers. 02:02:52

MR. NORTH: Your Honor, at this time we would tender -- no. Let me ask you this first. 02:03:03

BY MR. NORTH:

Q. Does the company generally prepare spreadsheets like this as a part of the tracking and trending practice? 02:03:13

A. Yes.

Q. And are these spreadsheets maintained as a part of the company's routine business activities?

A. Yes.

Q. And is it a regular practice to do so? 02:03:23

A. It is.

Q. And are you personally familiar and have seen before this output and this example of the tracking and trending through December of 2016?

A. I have. 02:03:37

MR. NORTH: Your Honor, at this time we would tender 5874.

MR. O'CONNOR: Objection. Lack of foundation, hearsay and 403.

THE COURT: Why don't we talk about that for a minute? 02:03:50

Ladies and gentlemen, if you want to stand up, feel free.

(Counsel meet at sidebar.)

THE COURT: What's the basis for the hearsay 02:04:08

objection? 02:04:09

MR. O'CONNOR: Well, right now it's an out-of-court statement.

THE COURT: Well, I know that. But he saw sought to lay foundation for a business record. 02:04:15

MR. O'CONNOR: But what is the basis of this? Where is the track TrackWise document? I can't tell if this was based all upon information they gathered in the regular course of their business.

THE COURT: Well, he testified to that. 02:04:28

MR. O'CONNOR: Well, which TrackWise data is what my foundation objection is about and how many documents, which documents?

THE COURT: Okay. Is there another basis for your hearsay objection? 02:04:40

MR. O'CONNOR: No. I mean, I think that they tried to lay the foundation for it as a business records exception except for that flaw that I'm arguing with you right now.

THE COURT: All right. Well, to authenticate a document under Rule 901(a) all you need to present is evidence 02:04:55 sufficient for the jury to find that the document is what it purports to be. The witness has testified it is the spreadsheet created from the TrackWise data and he explained what data is used, so I think that's a sufficient foundation and, therefore, I'm going to overrule the hearsay objection and 02:05:12

the foundation objection. And I don't think this has a 403 problem so I'll overrule the objection. 02:05:16

MR. NORTH: Thank you, Your Honor.

MR. O'CONNOR: Okay.

(End of sidebar discussion.) 02:05:24

THE COURT: Thank you, ladies and gentlemen. The objection is overruled. 5874 is admitted.

(Exhibit Number 5874 was admitted into evidence.)

MR. NORTH: Could we display this to the jury, Your Honor? 02:05:44

THE COURT: You may.

MR. NORTH: And for purposes of our discussion here, could we blow up, Mr. Russell, the first four columns so we can focus on those and be able to see them? Yeah, let's do the first four columns first. 02:06:10

BY MR. NORTH:

Q. Mr. Modra, let's walk through this. Does this contain the number of fractures, migrations, perforations, PE, PE with death, and tilt complications that had been reported with the Recovery filter, the G2 filter, and the G2 Express, G2X? 02:06:39

A. Yes.

MR. NORTH: And then if we could add a couple more columns over until we get to G2 rate.

Q. So what does this show is the rate of fracture for the G2 through all sales through December of 2016? 02:07:17

A. .24 percent. 02:07:23
Q. What does this show is the rate of migration calculated by the company for the G2 filter through December of 2016?
A. .16 percent.
Q. What does this show is the rate of perforation for the G2 filter through December of 2016? 02:07:42
A. .24 percent.
Q. Now, Mr. Modra, these aren't perfect calculations as to what the rate is in the real world, are they?
A. No. 02:08:07
Q. And would you believe that all 130,574 G2s that were sold over the years were actually implanted into patients?
A. No.
Q. In your experience in working with Bard, would you think that a large majority of the sales would have actually been 02:08:27 implanted?
A. Yes.
Q. And why is that?
A. Because people -- these are comparatively more expensive devices. You don't buy them to sit on the shelf and they have 02:08:44 a recently long shelf life so you have a long period of time -- shelf life meaning the time they can sit on a person's shelf before they implant it or use it. So in my experience, those things help contribute to more use.
Q. And you're not trying to tell this jury, are you, that 02:09:11

Bard has a report in its files of every single complication that has occurred with the G2 over the years; right? 02:09:14

A. No.

Q. And you're familiar with the concept that adverse events can be underreported; correct? 02:09:27

A. Yes.

Q. Does Bard and the Quality Department that you supervised for all those years, does it proactively go out and seek to find out information about every complication with IVC filters that it hears about? 02:09:45

A. Yes.

Q. Including complications reported in the medical literature?

A. Yes.

Q. And does that include all reports received from physicians? 02:09:53

A. Yes.

Q. Does that include all reports overheard or received from sales representatives in the field?

A. Yes. 02:10:06

Q. Does that include all reports received from the MS and S department in Covington, the hotline that people can call in?

A. It does.

Q. Is does that include all reports of complications that might be discussed at SIR conferences or something like that 02:10:23

that you get wind about? 02:10:26
A. Yes, it does.
Q. Does Bard Peripheral Vascular make every effort to find out and investigate about every fracture, migration, perforation, and tilt it learns about regarding its filters? 02:10:44
A. Yes.
Q. In your view, are these complication reports and the calculation of the rates the very best that you are able to determine based on the information that you can obtain?
A. Yes. 02:11:02
Q. Did the company and your department track these rates constantly throughout your time at Bard Peripheral Vascular?
A. Yes.
Q. And given the fact that you're still out there and in frequent contact with the employees that used to report to you, 02:11:28 are you aware of whether the company continues to do so on a regular basis now?
A. I know they do.
Q. Mr. Modra, at any time in all your dealings with the FDA in your work to address the warning letter reporting issues, in 02:11:46 your other conversations with the FDA, did the agency ever suggest to you that it wanted Bard to recall the G2 filter?
MR. O'CONNOR: Objection. Irrelevant. Calls for hearsay.
THE COURT: Overruled on relevancy. 02:12:05

What's your response on hearsay? 02:12:09

MR. NORTH: I believe we have had this same discussion with regard to Mr. Van Vleet.

THE COURT: If we did, I've long forgotten. Do you want to talk about it again for a minute? 02:12:18

Okay. Sorry, ladies and gentlemen.

(At sidebar 2:12.)

MR. NORTH: My recollection was that you indicated with regard to Mr. Van Vleet that if he said no, it would not be hearsay, because he's not saying anything that they said. 02:12:37 And then we had the discussion about silence, whether that was an assertion by silence. And because a recall -- I forget -- the Court looked at -- silence in this circumstance is not a statement assertion that would be hearsay.

MR. O'CONNOR: Well, I wasn't up here for -- 02:13:03

THE COURT: I'm not doing it because of that conversation.

What is your response on those points?

MR. O'CONNOR: Well, that is the out-of-court statement they want is silence, that nothing was done and so 02:13:13 there must have been no problems. And the FDHO is not --

THE COURT: So that's the hearsay objection?

MR. O'CONNOR: Yes.

THE COURT: All right. I did rule after looking at Weinstein's with respect to -- I can't remember who the witness 02:13:27

was that the case law makes clear that silence is an out-of-court assertion for purposes of hearsay only if it is intended by the speaker to be an assertion and there is evidence that the speaker intended it to be an assertion. There's no evidence that the FDA silence was intended to be an assertion and, therefore, it's not hearsay. That was my ruling before and my ruling now, so I'm going to overrule the hearsay objection. 02:13:30 02:13:46

(End of sidebar discussion.)

THE COURT: Thank you, ladies and gentlemen. 02:13:59

The objection is overruled.

BY MR. NORTH:

Q. Mr. Modra, during your time at Bard Peripheral Vascular and with all of your many dealings with the FDA, both discussions about the warning letter, reporting issues, and other matters, did the agency ever suggest to you that it wanted Bard to recall the G2 filter? 02:14:17

A. No.

Q. Thank you.

MR. NORTH: That's all the questions I have. 02:14:30

THE COURT: All right.

Cross-examination?

MR. O'CONNOR: Yes, Your Honor.

CROSS - EXAMINATION 02:14:35

BY MR. O'CONNOR:

Q. Hi, Mr. Modra. My name is Mark O'Connor.

A. Hi.

Q. Let me ask you about the FDA. The FDA operates on an honor system; right? 02:15:00

A. With regard to manufacturers?

Q. Yes.

A. Yes.

Q. It expects the manufacturers to be honest and forthright; correct? 02:15:09

A. That's correct.

Q. Somebody from the FDA cannot be at Bard every single day looking over your shoulder, can they?

A. No. 02:15:20

Q. And if the honor system doesn't work, it falls apart; right?

A. Yes.

Q. Let's look at Exhibit 1680. You talked about it but let's look at the warning letter. 02:15:35

MR. O'CONNOR: I believe this is in evidence, Your Honor.

THE COURT: It is.

MR. O'CONNOR: May we publish it to the jury, please?

THE COURT: Yes. 02:15:48

BY MR. O'CONNOR: 02:15:50

Q. A couple things, Mr. Modra. You agree that this is the warning letter that Bard received on January 13, 2005; correct?

A. It's July 13?

Q. July 13, 2015. And just so we're clear, this is an inspection; this isn't an audit; right? 02:16:00

A. This document?

Q. Well, it refers to there was an inspection at Bard; right?

A. Right.

Q. Thank you. And the warning letter addressed violations found at Bard; right? 02:16:15

A. It does.

Q. And if we go to the second-to-the-last page, page 11 of this letter. And if you look at the first full paragraph.

MR. O'CONNOR: Felice, are you able to outline that? 02:16:51

BY MR. O'CONNOR:

Q. There was no choice, Bard had to respond; correct?

A. Yes.

Q. I mean, it wasn't something that Bard was doing out of the kindness of its heart or on a good-faith basis; correct? 02:17:05

A. Correct.

Q. Bard had to respond in 15 business days; right?

A. Yes.

Q. And the failure to respond meant serious sanctions could be imposed upon Bard; right? 02:17:20

A. Correct.
Q. I mean, as a matter of fact, the FDA could prevent Bard from releasing or promoting products until this issue was resolved; right?
A. If we couldn't complete them in 15 days and if the reason for that delay wasn't suitable to FDA, correct. 02:17:36
Q. And you were responsible to include documentation of corrective actions; correct?
A. Correct.
Q. And take steps to show the FDA that this issue about complaint reporting was going to -- that you were taking steps to prevent it from ever happening in the future; right? 02:17:52
A. Correct.
MR. O'CONNOR: Let's go to page four, Felice. And look at number three, please. 02:18:24
BY MR. O'CONNOR:
Q. The violation was a failure by Bard to establish and maintain procedures for receiving and evaluating complaints as required by regulation; right?
A. That is what it says. 02:18:43
Q. And by the way, you and your attorney talked about an SOP and you showed one but that SOP that you showed us before was something that was prepared by your company in December of 2015; right?
A. I can't recall the date. 02:18:59

Q. I can show you the signatures. It was not the SOP, the standard operating procedure, that was in place at the time you received this complaint. 02:19:00

A. I'm not sure which one you're referring to.

Q. Well, we can talk about that in a moment but to keep things moving, the standard operating procedure, the SOP that you were using at this time, was from 2014; is that right? 02:19:13

A. For complaint handling?

Q. Yes.

A. We were using procedures long before that. 02:19:28

Q. And if you look down at particle A -- by the way, did you bring those standard operating procedures with you today that you were using at the time you received this warning better?

A. I didn't.

Q. And if you look at paragraph three, the FDA talked about your current complaint activities. Do you see that? 02:19:49

A. Yes.

Q. And the FDA warned Bard that your investigation procedures did not include adequate instructions for ensuring that complaints involving a device or device component provided by a supplier are adequately evaluated for root cause of the alleged device failure. 02:20:10

Do you see where I read?

THE COURT: That actually was not on the screen when you read it. 02:20:29

MR. O'CONNOR: I'm sorry. Can you get down to paragraph A? 02:20:31

BY MR. O'CONNOR:

Q. Do you see that last sentence on paragraph A?

A. I do. 02:20:36

Q. And did I read that correctly?

A. Yes.

Q. And root cause is very important in Bard's business, isn't it?

A. It is. 02:20:44

Q. When Bard becomes aware that devices like filters are failing, something that's available by Bard is to conduct a root cause analysis to determine what it is about the device that's causing it to fail.

A. A root cause investigation. 02:20:58

Q. And the whole issue about complaint handling and complaint reporting is important because it's a public database where your complaints go to; right?

A. If they are reportable, correct.

Q. And it's a public database that can be -- is accessible by physicians if they want to look there; correct? 02:21:11

A. Correct.

Q. It's important that a company like Bard is very accurate in the complaints and how they describe the complaints when it goes to that database; right? 02:21:26

A. Yes.
Q. I mean, you understand that there are doctors who are considering making risk-benefit decisions, helping their patients, and they look to that now and then to evaluate the risks and the benefits of devices; true? 02:21:41
A. I don't know that to be certain that that is the only thing they look at.
Q. Would that make sense to you?
A. It would.
Q. Now, what happened was the FDA found that there was a problem with how you described incidents; fair? If you look down at B, it talks about a complaint of a G2 Filter that embolized and it was an embolization of a detached filter arm with associated areas of hemorrhage and necrosis in the right lung. 02:22:27
A. Correct.
Q. Now, fair that we can tell the jury that's a serious injury?
A. That is a serious injury, yes.
Q. But Bard called it a malfunction? 02:22:43
A. We called it originally a malfunction before we had information that said it was a serious injury, including this hemorrhage and necrosis. We received that later, as I described earlier, and filed a supplemental report.
Q. I understand. You file the complaint without completing 02:22:58

an investigation; true? 02:23:00

A. No, that is not true. We conducted an investigation based on the evidence that we had. We received additional information -- and filed it with the FDA. We received additional information at a later point which outlined this and 02:23:12 refiled it with the FDA as patient death.

Q. This was a retrospective review?

A. No, it was not.

Q. You didn't have to go back and look at files?

A. For this one right here we didn't have to do that. We 02:23:27 identified it ahead of time even before the FDA came and had filed it.

Q. What you did was retrospectively went back and looked at complaints that you had received over the years, if any?

A. We conducted that but we didn't do that as a result of 02:23:42 this.

Q. I'm talking about what you did in response to the warning letter.

A. We did do that as a response to the warning letter.

Q. You went back and looked at patients who had filters that 02:23:50 were implanted as early as 2007, 2008; correct?

A. I don't recall the implant dates of the records that were reviewed.

Q. Well, is it fair to say that you had complaints that were reported to you and you looked -- they were reported to you as 02:24:09

early as 2013? 02:24:13

A. Correct.

Q. Did you look before you came here today to see if Sheri Booker's complaint was one of the complaints that was the subject of this investigation? 02:24:27

A. The investigation or part of the retrospective review?

Q. Did you look to see if her complaint was there?

A. I did.

Q. Was it there?

A. It was. 02:24:37

MR. O'CONNOR: If we go to page five.

BY MR. O'CONNOR:

Q. Here's more that were incorrectly described as malfunctions; is that correct? The G2 filter detached filter limb in the renal vein with an IVC wall perforation and blood-thinner treatment. 02:25:11

Do you see where I read?

A. I do.

Q. That is an injury; correct?

A. Correct. It's required to be filed. 02:25:23

Q. Express IVC perforation and aneurysm. That's an injury now you found out; right?

A. Correct.

Q. And if you go down another one, that was the subject of the inspection, was that there was a patient who had a G2 02:25:40

filter who experienced abdominal pain with filter legs protruding through the IVC wall and had to undergo percutaneous removal. 02:25:45

Did I read that correctly?

A. Yes. 02:25:59

Q. And that was subject of the inspection; true?

A. It was.

Q. And then as you go down, there was another one -- excuse me. There was also an issue about the complaints. If you look at paragraph C and those talk about complaints of ten patients who were exposed to schedule retrievable procedures to remove the IVC filter that were not successful. 02:26:15

Did I read that correctly?

A. Yes, you did.

Q. And the FDA, we'll be able to look at this in more detail, felt that the way your complaints were handled was inadequate; true? 02:26:42

A. That's what they stated.

MR. O'CONNOR: Now, let's look at Exhibit Number 2217. And go to the next page, Felice. 02:27:05

BY MR. O'CONNOR:

Q. Do you recognize this memorandum to you from Judy Ludwig dated January 23, 2015?

A. I do.

MR. O'CONNOR: Move Exhibit 2217 into evidence, Your 02:27:42

Honor. 02:27:44

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 2217 was admitted into evidence.)

MR. NORTH: May we display, Your Honor? 02:27:54

THE COURT: Yes.

BY MR. O'CONNOR:

Q. And if you look at this, Mr. Modra, the date is January 23, 2015, and the subject is IVC Filters Retrospective Review.

Did I read that correctly? 02:28:21

A. Correct.

Q. And this is what you all at Bard were doing in response to the warning letter that you received from the FDA; correct?

A. Yes.

Q. In an effort to avoid any penalties or sanction by the 02:28:35 FDA, you had to move on this; right?

A. Yes.

Q. And you had to take it seriously now, didn't you?

A. We were taking it seriously before.

Q. Well, earlier on direct examination you talked about a 02:28:47 number -- you made it a point to tell us about a number of events that were defined as serious injury that you found that you could change back to malfunction. Do you recall that testimony?

A. I do. 02:29:04

Q. But it went both ways, didn't it? For example, if you look at the last paragraph. 02:29:04

MR. O'CONNOR: Would you highlight that, please, Felice.

BY MR. O'CONNOR: 02:29:18

Q. And to be fair and balanced, I thought I heard you talk about that, the results of the retrospective review identified a total of 274 complaint records.

Did I read that correctly?

A. Correct. 02:29:29

Q. Which meet the definitions of malfunction and serious injury?

Do you see where I'm reading?

A. I do.

Q. And then you were -- you learned that 230 of the complaints identified as requiring supplemental filing to change reportability status from malfunction to serious injury. 02:29:37

Did I read that correctly?

A. That's correct.

Q. So while you talked about the ones that you were able to change from serious injury to malfunction, you actually had as many if not more that you had to go from malfunction to describe as a seriousness injury after reviewing the complaints and describing them accurately; true? 02:29:58

A. These were the ones I spoke about before. These were 02:30:13

after the retrospective or re-retrospective review downgraded back to malfunction as a result of discussing it with FDA. 02:30:18

Q. Well, the way I'm reading it, they were identified as requiring supplemental filing to change reportability status from malfunction to serious injury. 02:30:34

Did I read that directly?

A. That's correct. This was in January and after the discussion with the FDA later in the year, they agreed that we put those back to malfunction.

THE COURT: All right. We're going to break at this point. 02:30:46

Ladies and gentlemen, we will resume at 2:45.

(Jury departs at 2:30.)

(Recess at 2:30; resumed at 2:47.)

(Jury enters at 2:47.) 02:47:40

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor.

BY MR. O'CONNOR: 02:48:32

Q. Mr. Modra, we talked earlier about Exhibit 5560 which is -- you described it as an R002. Do you recall that testimony?

A. Yes.

Q. And you were talking about a document that was dated 02:48:44

January 15, 2007, but I take it that the R002 applied throughout the years? 02:48:47

A. Yes. R002 is a standard.

Q. And that was a protocol procedure to conduct failure investigations and prepare reports? 02:49:06

A. To determine whether it was required to take additional action of product in the field.

Q. All right.

MR. O'CONNOR: Let's look at Exhibit 2048, please.

BY MR. O'CONNOR: 02:49:25

Q. This is a failure investigation R002 history review. Do you recognize this type of a document?

A. The type of the document, yes.

Q. And this is a document that is prepared in accordance with Bard policies? 02:49:42

A. It looks like a summary of other documents.

Q. And prepared and maintained in the usual course of Bard's business; is that correct?

A. Yes.

MR. O'CONNOR: I would move to admit 2048, Your Honor. 02:49:56

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 2048 was admitted into evidence.)

\\\

BY MR. O'CONNOR: 02:50:03

Q. And let's go to page 11 real quickly if we will and this is a table that talks about chronology of events. Do you see that?

A. I do. 02:50:16

Q. And if you look down at October 17, 2003, and just below it, that is when Bard --

MR. O'CONNOR: May I publish, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR: 02:50:43

Q. And this is Bard's internal documentation about various failures and events that happened with its filters; true?

A. I'm not familiar with this particular document but that's what it appears to be.

Q. All right. It mentions -- it notes that on October 17, 2003, was the first migration complaint received from the field. Do you see that? 02:50:59

A. I see that.

Q. And that was about three months after the Recovery was launched into the market? 02:51:14

A. I can't remember exactly.

Q. Does it sound about right based upon your knowledge and history of the company?

A. I think so, yes.

Q. All right. And then just below it is another migration -- 02:51:23

excuse me. 11-29-2003. And there's a second migration within just a few months of the Recovery being launched. Do you see that? 02:51:36

A. Yes.

Q. And then if you go to the bottom, on February 9, 2004, and just seven months on the market, Bard was provided a complaint about the first migration complaint received from the field related to a Recovery patient death. Do you see that? 02:51:51

A. I see that.

MR. O'CONNOR: Greg, quickly, please, go to page 13 and go down to April 14, 2004. 02:52:19

BY MR. O'CONNOR:

Q. Do you see that, Mr. Modra? On April 14, 2004, is the second migration complaint received from the field regarding a patient death who had a Recovery filter. Do you see that? 02:52:35

A. I don't see where it says the filter type.

Q. Pardon me?

A. I don't see where it says the filter type.

Q. Well, you're aware that the Recovery was associated with deaths in patients; correct? 02:52:54

A. Correct.

Q. And if you assume that this is a Recovery filter, that would be just months after the launch. This is April 14, 2004. You see that?

A. I do. 02:53:08

Q. All right. Thank you. 02:53:09

Let's go to page 15. And if you scroll down to May 17, 2004, and, again, assuming this is the Recovery filter, Bard is now aware that on May 17, 2004, just eight months after the release of the Recovery to the market is the third migration complaint received from the field related to a patient death. Do you see that? 02:53:38

A. I see that.

Q. This is all going on within the first year, correct, first year of release? 02:53:51

A. If the date of release was August, then that would be within the first year.

Q. And then scroll down to the next one, June 15, 2004, and here just shortly after is the fourth Recovery migration-related death. Do you see that? 02:54:18

A. I see.

Q. And Bard continued to sell the Recovery; correct?

A. Yes.

MR. O'CONNOR: And then if we go to page 30, and go to the bottom, Greg. 02:54:36

Q. The G2 filter was cleared on August 29, 2005, as a permanent filter?

A. That sounds correct.

Q. And Mr. Modra, there was no clinical trial, no clinical study done on the G2 before it was launched into the market as 02:54:57

a permanent filter; true? 02:55:01
A. I'm not familiar with it.
Q. Are you aware -- you're not aware of any clinical study that was done by Bard before releasing the G2 as a permanent device into the market, are you? 02:55:15
A. No.
Q. And when did you come to Bard?
A. August of 2000.
Q. Pardon me?
A. August of 2000. 02:55:27
Q. So you were there for the release of the G2 as a permanent --
A. I was at a completely different division.
Q. Pardon me?
A. I was at a completely different division and location. 02:55:35
Q. But when you became involved in filters, did you become familiar with the history?
A. Some of it, yes.
Q. Did you ever ask Bard why the G2 was launched as a permanent device without first doing a clinical study? 02:55:46
A. I didn't.
Q. All right. But if you look at the bottom there, within three months of release, Bard had already received 20 complaints regarding the G2 for caudal migration. Do you see that? 02:56:06

A. I do.

MR. O'CONNOR: Let's quickly talk about Exhibit 5874, please.

BY MR. O'CONNOR:

Q. You talked about this particular exhibit with your attorney on direct examination. Do you recall that?

A. I do.

Q. Do you know how many patients out there had G2 filters that had fractured or migrated that were asymptomatic?

A. I don't.

Q. I mean, do you know how many patients were out there that had fractures, migrations, perforations, or tilts who had not become a complaint as of the time this table was prepared?

A. I don't.

Q. You know from your experience at Bard that there are patients who have complications from both the Recovery and the G2 that don't have any symptoms from a fracture or a migration; right?

A. Yes.

Q. And so there's no way that you can tell this jury how many people may be walking around in our country who have a failed G2 filter in their body and are not aware of it; true?

A. No, and failed would be failed to perform its intended use or intended --

Q. You don't know how many people are walking around with a

fractured, migrated, or tilted G2 filter; true? 02:57:42
A. I don't.
Q. And when we look at these numbers, we look at the 312 G2 fractures, 207 migrations, 316 perforations, and then 320 tilts. How many patients had more than one of those 02:58:17
complications that is noted on this exhibit?
A. I can't tell from there.
Q. But you know there are patients out there who have migration, who then goes to tilt, that goes to perforation, goes to fracture and then embolization. You know those happen 02:58:40
with the G2 filter; correct?
A. I've read reports of those, correct.
Q. And do you do anything to record those who have had the cascade of all or more than two of the failures?
A. We report each and every one of those failure modes. We 02:58:56
record it in the narrative and we report it as an MDR accordingly.
Q. Well, you get this data from the MAUDE database primarily, don't you?
A. No. I get it from the internal complaint database. 02:59:11
Q. Okay. And is that -- does that include complaints that do not go to the MAUDE database?
A. The internal complaint database would but these in particular are all reported in the MAUDE database.
Q. And you know that the MAUDE database is defective for 02:59:27

being underreported; correct? 02:59:33
A. In the industry we know that there's underreporting.
Q. But do you report to doctors on a regular basis that as of the date of this document, as of December 16, did you send out an email blast or contact your doctors and say, "There are 312 fractures in the G2 that we are aware of and there may be more"? Have you sent that kind of a -- 02:59:46
A. No. No. We don't send that.
Q. You don't share the information that is in this exhibit with doctors; fair? 03:00:04
A. Well, these are reported in the MAUDE database so they would be on the MAUDE database.
Q. I'm talking about this exhibit.
A. No.
Q. This is Exhibit 5874. You don't put together a document like that and send that out to the doctors, do you? 03:00:16
A. No.
Q. You keep that in house; right?
A. It's -- these numbers aren't reflective of the exact actual rate. There's a lot of variability to those. 03:00:27
They are useful for comparisons between the generations but beyond that, they are not reflective of the full actual rate.
Q. Mr. Modra, these numbers are people; right?
A. I understand that.
Q. They are people with names; right? 03:00:44

A. Some my relatives. 03:00:47
Q. And they are people who have experienced complications from the Recovery and the G2 filter and all the Bard filters; correct?
A. I take that seriously. 03:00:57
Q. And you are aware of very serious injuries that have happened to people and even death who have received the Recovery; correct?
A. That's correct.
Q. And you are aware of people who have had the G2 who have 03:01:10 experienced injuries that have required them to go in and have open -- excuse me.

MR. O'CONNOR: May I publish this exhibit, Your Honor?

THE COURT: Yes. 03:01:24

BY MR. O'CONNOR:
Q. And we were talking about the G2. Again, these are complications that you had in your database as of December of 2016 correct?
A. Correct. 03:01:41
Q. And as we said, this does not include people who may have the complications who have not seen a doctor and who have not reported symptoms; right?
A. Correct.
Q. But you know from your experience at Bard that there are 03:01:51

patients who have had filter complications that have landed them in the hospital and necessitated very complex complicated surgeries; correct? 03:01:53

A. Correct.

Q. And even one of those patients is too many? 03:02:05

A. That is --

MR. NORTH: Objection, Your Honor. Argumentative.

THE COURT: Sustained.

BY MR. O'CONNOR:

Q. Now, just so we're clear, this is a document that is not provided to your sales force; true? 03:02:35

A. True.

Q. And the sales force at Bard is the face of the company. They are the interface with your customers, the doctors and the hospitals; correct? 03:02:55

A. Primarily, not the only one but primarily.

Q. And you know that doctors rely on the sales force to provide them with accurate and truthful information about your devices; true?

A. True. 03:03:05

Q. And yet this exhibit is something and this information is something that is not provided to your sales force; correct?

A. Correct.

Q. And it's not provided to doctors; true?

A. True. 03:03:19

Q. I think that's all I have. Let me check. 03:03:23

MR. O'CONNOR: Thank you.

THE COURT: All right.

Redirect?

MR. NORTH: Yes, Your Honor, just a couple of 03:03:29
questions.

Could we bring 5875 back up, please. That's not the one we had. The last exhibit that was just up?

THE COURT: 5874.

MR. NORTH: I'm sorry? 03:04:13

THE COURT: 5874.

MR. NORTH: Could we display this to the jury, Your Honor?

THE COURT: Yes.

REDIRECT EXAMINATION 03:04:22

BY MR. NORTH:

Q. Mr. Modra, you were asked a number of questions about this document and I just want to be clear it's clear. You're familiar that the Recovery filter was the first generation Bard filter? 03:04:32

A. First retrievable filter, yes.

Q. And then what was that followed by?

A. G2.

Q. And then the G2 Express, G2X?

A. Correct. 03:04:45

Q. Did the Eclipse Filter follow the G2 filter? 03:04:46
A. It did.
Q. And then the Meridian filter?
A. Correct.
Q. And then is the Denali the retrievable filter that Bard is 03:04:50
selling today?
A. It is.
Q. So there's essentially been six generations of retrievable filters?
A. That's correct. 03:05:02
Q. Now, you were asked some questions about this data and how it was derived. Is this the best data that the company is able to obtain about the occurrence of complications with the company's filters?
A. It is. 03:05:15
Q. Thank you.
MR. NORTH: That's all I have.
THE COURT: All right. Thank you, sir. You can step down.
(Witness excused.) 03:05:20
MR. NORTH: Your Honor, at this time the defendants would rest.
THE COURT: All right. The defendants have rested.
Plaintiff's counsel, do you have any rebuttal evidence that you wish to presented? 03:05:40

MR. O'CONNOR: No, Your Honor. 03:05:41

Your Honor, the issue we talked about earlier about moving another guideline in. I think you were going to take that under advisement.

THE COURT: Well, you need to identify the exhibit. 03:06:05
What is the other exhibit you're moving in?

MR. O'CONNOR: One moment, Your Honor. At this time we would move in Exhibit 6842.

MR. NORTH: No objection, Your Honor.

THE COURT: All right. What's that number again? 03:06:33

MS. REED ZAIC: 6842, Your Honor.

THE COURT: 6842. All right. 6842 is admitted.

(Exhibit Number 6842 was admitted into evidence.)

THE COURT: Any additional rebuttal evidence?

MR. O'CONNOR: Nothing from the plaintiff. 03:06:47

THE COURT: All right.

Counsel, would you approach for a minute, please.

(At sidebar 3:07.)

THE COURT: Counsel, how long do you think your closings are going to take? 03:07:23

MR. LOPEZ: About an hour and 15.

THE COURT: Well, you don't have that much time left so we'll need to talk about that. You've got about 50 minutes left. You've used over 50 minutes today but you'll use all of it? 03:07:38

MR. LOPEZ: Yeah. 03:07:40

THE COURT: How about from the defense?

MR. NORTH: An hour and 15, give or take five or ten.

THE COURT: Okay. We've gained an hour in jury deliberations because the Fourth Avenue Garage is closed on 03:07:52 Friday and so because it's Cesar Chavez Day and that garage is owned by the City of Phoenix and the City is going to close, so the jurors have been told that they have to park at a garage where they need to be in the garage by 7:30 Friday morning. And the jurors in response said, "That's great. We would like 03:08:14 to start at 8," so they will be deliberating at eight so we've gained an hour of deliberation.

So I'm thinking we ought to go ahead and break for the day, talk about the couple of issues that remain and then plan to start tomorrow with instructions and argument. Does 03:08:29 that make sense to you?

MS. REED ZAIC: Yes, Your Honor.

MR. NORTH: I think we would all like that.

MS. REED ZAIC: On that note, I do need to supplement and renew our request for a limiting instruction based on the 03:08:41 last 25 minutes of his testimony.

THE COURT: Which is what?

MR. NORTH: Can we address that outside the presence of the jury?

THE COURT: Hold on a minute. If it's related to 03:08:51

this testimony, I want to know what it is. 03:08:53

MS. REED ZAIC: He testified that Mr. Modra testified that the FDA never sent the warning letter about the design of the device and I think that goes to the FDA commenting or not commenting on the safety and efficacy of the device, and a 03:09:12 limiting instruction would reiterate that the 510(k) clearance process is not about safety --

THE COURT: So you're not talking about a limiting instruction. You're talking about that proposed 510(k) instruction and the jury instructions? 03:09:23

MS. REED ZAIC: Yes. Yes. Okay.

THE COURT: Okay. Let's deal with that in the jury instructions.

(End of sidebar discussion.)

THE COURT: All right. Ladies and gentlemen, we have 03:09:43 finished the evidence in the case so the next two steps are I'm going to give you jury instructions. They will take about 20, 25 minutes and then we're going to hear the closing arguments from the parties. There are a couple of legal issues I need to talk over with the parties to settle those jury instructions, 03:10:02 which could take us 15 or 20 minutes. I don't want to keep you waiting for that. So if it's all right with you, we'll break for the day now. When you come back in the morning, we'll give you the jury instructions, we'll do the closing arguments and then you'll begin deliberating tomorrow. 03:10:19

And I know we've gained an hour on Friday because of a parking garage issue. You all need to be here earlier and I understand you want to start at eight on Friday. You'll be deliberating by that time. There won't be anything in the courtroom so we're gaining somewhat the hour we're losing now in terms of trial time. 03:10:23 03:10:34

So we'll go ahead and excuse you at this time. Please remember not to discuss the case yet. We'll plan to begin tomorrow morning at nine with instructions and closing arguments. 03:10:49

We'll excuse the jury.

(Jury departs at 3:10.)

THE COURT: Please be seated.

All right. Counsel, as of now, plaintiff has used 29 hours and nine minutes; defendant, 24 hours and 12 minutes. 03:12:14

MR. NORTH: Can I say something on the time, Your Honor? I don't think it needs to be said but I just want to make sure. There was some talk earlier in the trial about if we didn't use all our time, maybe somebody else would get more, but we of course want to reserve that time for our closing and for punitive damages phase. 03:12:33

THE COURT: I didn't assume you were offering it up.

MR. NORTH: Just wanted to be certain, Your Honor.

THE COURT: Okay. Let's talk about a few issues.

Mr. North, you have been wanting to make a motion. 03:12:53

Why don't we go ahead and deal with that now? 03:12:57

MR. NORTH: So is now the time, Your Honor?

THE COURT: Now is the time.

MR. O'CONNOR: We're going to readjust our dugout.

THE COURT: That's fine. 03:13:09

MR. NORTH: Your Honor, this was the motion that the Court specifically gave us permission to reserve at the end of the plaintiff's case pursuant to Rule 30 and it's timely because it's now at the conclusion of all of the evidence. So we would be renewing the same motion that we had reserved at 03:13:34 that time and two for the price of one, all with one argument, but it's the same motion that we would have articulated at the end of the plaintiff's case and repeat now.

Your Honor, in this case we believe that the evidence is much different than it was at the summary judgment stage. I 03:13:54 understand that this court denied summary judgment. But then we don't believe the evidence is the same and, therefore, we would move for judgment, as a matter of law, under Rule 50, both as to the warning claim and as to the claim for punitive damages. 03:14:15

As to the warning claim, there are two issues: The adequacy of the warning and the causation between the warning and the injury to Ms. Booker. The plaintiff's argument at the summary judgment stage was principally focused on evidence of higher complication rates with regard to the G2. They relied 03:14:32

on things like the evidence of Dr. Betensky, the Harvard statistician. That was one of their experts. 03:14:38

They did not bring into this courtroom in this trial evidence of higher complication rates. They assumed higher complication rates in the context of many of their questions. 03:14:53
But actually to present evidence to the jury, we don't believe they did.

This Court had previously held under *Daubert* that neither Dr. Muehrcke or Dr. Hurst who testified as to those -- the issues like that could not talk about rates and did not 03:15:12
talk about rates. Dr. McMeeking specifically admitted on the stand that he had made no assessment of rates.

So the major thrust of their claim that G2 somehow has higher complication rates than other competitive filters on the market, we submit there simply is no evidence on this 03:15:34
record to support that.

Other than rates, their only criticism of the adequacy of the warning -- Dr. Muehrcke was not allowed to talk about it because it was outside his report -- was Dr. Hurst. He tried to say that the IFU did not point out the severity of 03:15:53
these injuries and these complications and what they could be. But the evidence is abundantly clear that the medical community, including Dr. D'Ayala, who implanted the filter in this case, are well aware of these complications and their potential severity. And, again, Dr. Hurst presented no 03:16:12

evidence that the Bard complication rate is higher than those of competitive filters. 03:16:18

Now, also with regard to the causation claim, we feel that they have -- and submit that they have not met their burden of proof on causation. There have been a lot of allegations slung around in this case, in this courtroom about Bard should have warned this, Bard should have warned that, but there is no evidence, we submit, that a different warning or an additional warning would have made a difference in the treatment to Ms. Booker, in the injury to Ms. Booker. And the issue in this case is not whether Bard could have provided better warnings to the universe. The question is whether our warnings to Ms. Booker's implanter were a proximate cause of her injuries. 03:16:30 03:16:51

The Court's motion for summary judgment was based on the predicate that Dr. -- and I can never say his name -- D'Ayala said that he would have used a different filter if he knew the G2's filter complication rates were higher. But, again, they haven't laid the predicate for that to be a basis for the failure to warn claim, we submit, because they have not submitted evidence of higher complication rates with the G2. 03:17:09 03:17:32

Also, how could the IFU possibly be a cause of the injury here. But given the testimony from the implanter? It is the plaintiff's burden of proof, and they never asked him whether he read the IFU. And, therefore, he never testified 03:17:52

that he read the IFU. He testified that he did -- he knew it was available and that is all he said. That's not proof under their burden that he read the IFU in a way that any inadequacy of the IFU could be a proximate cause of the injury. As far as what he was told with Bard sales representatives, we don't know. He testified unequivocally that while he knew the Bard sales rep, he did not recall any specific conversations regarding Bard filters. 03:17:57 03:18:18

That is not sufficient, we submit, to say that a failure to warn is about something by the sales rep could have been a cause. He may have had conversations and didn't recall them. We just don't know because this physician did not recall any conversations specific to the filter. Again, we submit that is not sufficient under the plaintiff's burden. 03:18:36

The doctor's testimony here is speculative. The predicate of higher application rates by the G2 has not been established and, therefore, on the issue of whether the warning could have been a cause of Ms. Booker's injury, we don't believe the plaintiffs have met their burden of proof. 03:18:57

Turning to punitive damages, the basis of the Court's denial of summary judgment in reading back through this, the order, is that the evidence that the G2 was less safe than the Simon Nitinol filter, that the G2 was failing at higher rates than competitors, and also based upon the Recovery filter evidence, the migration deaths, there was a mention of the 03:19:14 03:19:35

crisis communication plan, and there was -- the Court stated in that order -- and, again, I am -- I am quoting here that Bard knew -- there's evidence that Bard knew the G2 was failing at a significantly higher rate than other IVC filters but did nothing to correct the problem or to warn doctors or patients of the increased risk. 03:19:39 03:19:57

Your Honor, we believe after the trial, the evidence submitted here is much different than the evidence the plaintiff's submitted in that omnibus statement of facts they presented at the summary judgment stage. And also it's important that under Georgia law, a showing for punitive damages is not a preponderance of the evidence. It's a clear and convincing evidence standard, a standard that leads many Georgia trial judges to grant directed verdicts as they are still called in Georgia, or JNOVs, on punitive damages because it is a more onerous standard. It requires a higher level of proof than just more probable than not. 03:20:12 03:20:32

Here we believe the trial record, regardless of what is taken in the light most favorable to the plaintiffs, the MSJ record may have shown, the trial record does not support a clear and convincing evidence of punitive damages. The Court, at the summary judgment stage, cited evidence that G2s failed at a higher rate than competitors. The plaintiffs didn't present that complication data here. There was no rate evidence like that at this trial. 03:20:51 03:21:11

Your Honor, we believe that now that this trial evidence has come in, too, the relevance of these Recovery filter migration deaths and the lack of relationship to the conduct involved with Ms. Booker is clear. Every witness asked, including the plaintiff's own experts, admitted that they were not aware of a single instance of the G2 migrating to the heart and causing a death in the patient. It is our position, therefore, that evidence of what the Recovery filter may have done in those 19 deaths of migration to the heart is very dissimilar than what is occurring and has occurred here with the G2 and should not be evidence warranting a punitive damage award related to the G2 filter. 03:21:16 03:21:30 03:21:52

In fact, the evidence is -- we would say runs counter to any suggestion that the Recovery filter evidence justifies a punitive award. The undisputed evidence here is not only has there been no migration deaths, but Bard's attempt to redesign the filter to increase its migration resistance solved the problem of cephalad migration to the heart because they have 130,000 sold and there has not been one single report of a migration to the heart death. Yes, that were caudal migrations, a new phenomenon that happened here, but that's apples and oranges. And as everybody admitted, caudal migration is not the same thing as cephalad migration. It is not the health risk that cephalad migration is. 03:22:17 03:22:40

There's no evidence on this record that the G2 was 03:22:59

failing at a significantly higher rate than competitors. There's no identification of the increased risk allegedly associated with Bard filters and, in fact, the only evidence on this record is that Bard continued to improve its filters generation by generation. 03:23:02 03:23:19

The last exhibit I talked about with Mr. Modra is the most compelling evidence of that. The best evidence available of complication rates show that there is significant improvement in these complication rates, while all low, in every generation of filters. 03:23:37

And, Your Honor, I submit that that is antithetical to the sort of conduct that would give rise to clear and convincing evidence of egregious behavior warranting a punitive damages award under Georgia law. I submit to you, Your Honor, that if this is a punitive damages case based upon the evidence presented in this courtroom in this three weeks of trial, then every case, just about, in a product liability context, is a punitive damages case. 03:23:54

And I think to make every case a punitive damages case would eviscerate the intent of Georgia's General Assembly when in the 1990s they passed a tort reform legislature which included the punitive damages provision that increased the burden to get an award o and punitive damages to clear and convincing evidence. 03:24:11

Punitive awards are the exception, not the rule. And 03:24:33

we submit that on this record, with this evidence at this trial, there simply is not evidence that would pass must under that standard and, therefore, we submit that both on the warning claim, for the reasons I stated, and on the punitive damages claim, Bard is deserving of judgment, as a matter of law. 03:24:36 03:24:50

Thank you.

THE COURT: All right. Thank you.

Plaintiff response?

MR. MANKOFF: Josh Mankoff for the plaintiff, Your Honor. 03:25:06

I would like to begin by discussing the issue by Dr. D'Ayala because it is perhaps the more focused issue. As you heard from Mr. North, there's no contention that he said he never read the IFU. Quite to the contrary, he was asked if he relied on the instructions for use and his answer was yes. He also stated he relied on other information including information from colleagues and medical literature, and he specifically remembered being called on by the sales representative who testified in this case, Mr. Ferrara, and he was asked whether adverse events associated with the Nitinol or the G2 were ever discussed with him by any sales representatives that called on him and his answer was no. 03:25:18 03:25:38

So we submit that that is clear evidence that even if we had to rely on the instructions for use, that if they had 03:26:00

been in there or he had gotten information from the sales representative, that would have made a difference in this case. 03:26:06

Of course you also heard testimony that all of the literature and brochures as presented counts as labeling and needs to be fair and balanced, so any of that could have also had any of the information that Bard had about the issues with G2 filter and failed to give. 03:26:22

To the contrary, I don't know the exhibit number of the box that is sitting here in front of us, but although it's a permanent device, it says Recovery on it. And that is something that the FDA addressed. They made Bard change the name from Recovery to G2 because of its permanent labeling at that time. 03:26:42

Now, as far as the adequacy of the warning, plaintiffs are not limited to showing that there was a difference in rates between the G2 and another filter, although that evidence is in this case, but the issue is much broader than that. Information that Bard had about problems with the G2 filter and the Recovery filter as well, because they are linked, and the G2 was based on the Recovery and it was from, you know, specific design changes that were made after they encountered problems with the Recovery filter. So information about problems with either filter that should have been conveyed and was not goes to the adequacy of the warning as well. 03:27:10 03:27:32 03:27:53

So that brings in all of the design evidence which Bard is not making a motion on here. So in effect conceding there's enough evidence there that there's a defective design. 03:27:53

So specifically, the story starts with the Asch study where Bard started with a pilot study and quickly encountered problems. They had a migration, they had two fractures. They investigated but never determined a root cause of the problem which becomes relevant when they started developing the G2 filter. 03:28:26

They promised Dr. Asch that they would do a study but of course we heard that they didn't do that. 03:28:43

Instead, they launched the filter onto the market and waited to see what would happen. And we saw evidence that the Recovery filter started failing. Very quickly, Dr. Cohen encountered a problem, he investigated, he found there were six deaths that had occurred. 03:29:07

And we saw evidence of migrations as well. They kept the Recovery on the market so they could use it as a predicate device for the G2 filter. They made design changes to address some of the problems that they saw with the Recovery but not all of them. 03:29:31

We heard from I believe it was Mr. Carr that they didn't focus on tilt or perforation and then we saw evidence that that was occurring with the G2 filter, both in their bench tests, so they were aware that was occurring, and then once 03:29:49

they launched it, also out in the field. 03:29:52

They had no idea, because they didn't -- we saw evidence that they didn't do additional fracture testing on the G2 filter. They had no idea if the changes they were making would work. They didn't do another pilot study. They didn't 03:30:10
do a clinical trial. They launched it to the market as well claiming substantial equivalence with the Recovery filter.

Meanwhile, when they did have bench tests that referenced the SNF filter that failed so they changed the standard. When they did hook removal tests, it also failed the 03:30:34
50 millimeters of mercury standard. It could only resist migration up to 35 millimeters of pressure.

Once launched and they started getting reports in of caudal migration, they did an analysis and they determined that it was unacceptable and they changed that standard as well. 03:30:55

We heard from Dr. Altonaga that physicians expect Bard to have an awareness of the long-term clinical performance of the device and that the actual number of failures was substantially higher than what comes in through the reports.

So to rest on that last exhibit we saw, for example, 03:31:25
where there were a few hundred reports of failures, Dr. Ciavarella also testified that we can multiply by 10 to 20 times to figure out exactly how many failures there are.

Once the EVEREST trial was completed, they had specific rates for what was going to happen with the G2. Even 03:31:49

though this was not a long-term safety study and it completed after six months of follow-up, that was still a 12 percent caudal migration rate, a 1.2 percent fracture rate, 18 percent tilt rate, and 26 percent of the filters penetrated. 03:31:53

We saw evidence that they had few, and in many cases no reports of such failures with the SNF filter. So right there is a difference in rates that they are complaining of wasn't shown. 03:32:11

Ms. Hudnall agreed that the company's responsible for giving risk-benefit information to doctors and doctors need this information for informed consent and that doctors should be told if Bard knew that the filters were tilting. So, again, all of this gets incorporated into the information that Bard should have provided and there's no evidence that they did provide to any doctor, let alone Dr. D'Ayala. 03:32:35 03:32:53

Ms. Wong also testified that the G2 was not statistically the same as the Recovery and that it would be wrong to say that it was as good as the SNF filter so another comparison that came out unfavorably for the G2 filter.

We also saw statistical comparisons with competitor filters, Exhibit 2243. And there was a statistically significant difference in deaths between -- for the Recovery versus the Greenfield, SNF, and some other competitor filters. 03:33:26

Dr. Streiff testified that the IFU for the G2 was inadequate and Dr. Muehrcke testified that doctors would have 03:33:57

wanted to know about these Bard internal findings about the caudal migration, about the unacceptable risk. He stopped using Bard filters when he found out about this information. 03:34:01

And we saw the marketing materials, as I mentioned, the box, but the brochure and the other materials made claims about the superiority of the G2 filter which we saw was not true. 03:34:25

We heard from Dr. Ferrara that he would not --

THE COURT: Counsel, we don't need to go through every witness. Let's use bigger picture arguments, please. 03:34:48

MR. MANKOFF: Yes, Your Honor. So as far as -- so some of that information that I described, of course the knowledge, the awareness of the risks, of the conscious disregard for the risk, goes as well to punitive damages. Mr. Carr agreed that it was a legitimate concern that the filter in the Asch study might have migrated further but it was caught because there was monitoring. 03:35:07

At the time in that trial, we heard evidence that they instituted additional monitoring to make sure not to harm patients. That was dispensed with once that trial ended. They monitored again more in the EVEREST trial than with the public but the failure to notify doctors that they should be monitoring patients for this issue when they were conscious of this risk also goes to the punitive damages. 03:35:39

The problem with the G2 was also a unique problem. 03:36:05

As you heard, it's that downward movement that was unexpected and led to a cascade of failures. And they learned that very quickly and rather than tell anybody, they started downplaying the risk. Dr. Ciavarella asked why not use the SNF when the G2 was on the market as a permanent filter. But at no time -- we heard about a brief time, I think a two-week period for the Recovery filter, when they paused selling it but at no other time did they stop selling the filter. Their focus was on keeping it on the market in order to get the next generation going and to not lose market share. 03:36:08 03:36:28 03:36:54

Dr. Lehman at the beginning said we shouldn't focus on selling it. We should focus -- or on getting a retrievable indication; we should focus on stability. They ignored that advice.

And they determined they needed to design a caudal Push Test. This was before Ms. Booker got her filter; but, again, they didn't tell anybody about that or stop selling the filter. They didn't tell the FDA about that. Instead we had at that same time we had Mr. Ferrara out with his brochures selling the filter and talking about the benefits. 03:37:15 03:37:38

The conscious disregard of the risk goes through all of their studies. I mentioned some of them. The failed migration-resistance testing against the SNF. Exhibit 1517, we haven't seen it up on the screen --

THE COURT: Counsel, you have been going for almost 03:37:58

20 minutes. Let's try to wrap this up in the next few if we can. We've got a number of other issues we need to address. 03:38:00

MR. MANKOFF: Sure.

Your Honor, I'll conclude by pointing out that this evidence falls into the categories that you mentioned when you denied the motion for summary judgment. Bard never appropriately tested its devices. They never took action to stop sales of the device when they knew of the problems. They learned of more problems with the EVEREST trial. And at the end of the day, this was about profit. They had marketing and sales, incentive bonuses. There was evidence that they needed a new device in order to maintain and grow market share. They stated that users would be swayed by aggressive marketing, even with negative clinical experience, and they went out and tried to grab a $172 million market. 03:38:26 03:38:45 03:39:07

If there are no further questions, I'll rest.

THE COURT: Okay. Thank you. Give me just a minute.

All right. I've just taken a moment to review my notes on the D'Ayala testimony. I'm going to deny the motion. I think there is enough evidence for this to go to the jury both on the failure to warn claim and on the punitive damages claim. 03:40:31

All right. Defendants, you want to make a motion; is that right? I'm sorry, plaintiff.

MR. STOLLER: Do you want our motion on judgment, as 03:40:47

a matter of law. 03:40:49

THE COURT: I do and I would like to do this in about five or seven minutes per side.

MR. STOLLER: We've got two. I'll handle the first which is as to the claim by defendants for comparative fault as to Dr. Amer -- and I'm specifically, Your Honor, going to talk about the element of causation and that they have made no proof of any causation such that they could -- would you like me to do it from here or the podium, Your Honor? 03:40:57

THE COURT: Please. 03:41:19

MR. STOLLER: And I will particularly brief on this one, your Honor.

As you know, they have pointed to Dr. Amer as being a non-party at fault which requires them to demonstrate both that he failed to comply with the standard of care and that that failure caused an injury to Ms. Booker that is at issue in this lawsuit. It's on the latter element where they fail and, in particular, under Georgia law -- and I think we'll talk about these cases a bit when we come back to intervening cause, superseding act on Dr. -- and I'm going to go with Dr. S, because I'm not sure I can pronounce his name appropriately. But under Georgia law, the party with the burden has got to establish causation. And when you're talking about medical cases, the case in Georgia is a case called ***Zwiren***, I might not be pronouncing that correctly, Z-W-I-R-E-N. It's 578 S.E. 2d 03:41:35 03:41:53 03:42:11

862. It is the Supreme Court of Georgia from 2003. 03:42:19

They are very clear, Your Honor, that if you're going to take on medical issues here and medical malpractice and claim negligence, you've got to prove both the standard of care and causation by expert testimony. And what we don't have for 03:42:36 Dr. Amer, Your Honor, is any testimony that his negligence caused harm. You had some testimony from Dr. Cousin who said that Dr. Amer should have apparently picked up this filter fragment at the time of that one study, but he didn't opine as to what would have happened had he done so. In other words, 03:43:04 there was no testimony that had Dr. Amer done so that there would have been a filter retrieval, removal or any action taken. Dr. S, Dr. Sobieszczyk, or however it is pronounced, likewise did not provide any testimony that met the standard for proof of causation beyond speculation that something should 03:43:22 have happened at that point, some action should have been taken that would have resulted in the filter being retrieved or that -- or that would have avoided any injury to Ms. Booker.

Rather, what you heard from Dr. S was, "I would have." Nothing about standard of care. Nothing about what 03:43:40 doctors would do but, "I would have."

And, in fact, when pressed about questions -- and I'm going to leave it here. But when pressed about questions what you would have done with filter fragments, he indicated with a filter fragment in the heart, he would have left it. There's 03:43:55

no testimony from Dr. S that anyone should have done anything and -- or expert testimony to the fact that something should have happened as a result of that that would have taken an action to -- and not -- or that the failure to take action or do anything at that point caused injury to Ms. Booker. 03:43:57 03:44:12

That's an essential element to their claim of his comparative fault and absent that, you can't go to the jury. They would be asked only to speculate as to what should have happened based on the alleged negligence of Dr. Amer.

THE COURT: All right. 03:44:30

Ms. Helm?

MS. HELM: Your Honor, I apologize, I don't have a hard copy so I have a case on my laptop. Your Honor, the case cited by plaintiff's counsel, ***Zwiren***, holds that there's no magic language or expert opinion on proximate cause in a medical malpractice case. That case was decided in 2003. 03:44:47

In 2014, the Georgia Court of Appeals cited -- decided the case ***Moore v. Singh***, S-I-N-G-H, which is at 755 S.E. 2d, 319. ***Moore v. Singh*** is on all fours with the case before this Court. In that case, a Dr. Borkan testified to the standard of care for an nephrologist. He testified that the nephrologist violated the standard of care by failing to read or report on an x-ray. 03:45:15

In this case, Dr. Cousin testified about the standard of care and they aren't challenging that. In ***Moore v. Singh*** a 03:45:36

separate doctor who did not offer a standard of care opinion testified that had the condition of the fracture been discovered -- I want to make sure I read it -- it could have been treated without surgical intervention. That's exactly what Dr. Sobieszczyk testified to today. 03:45:41 03:46:00

If the -- if the fracture and the condition of the filter had been reported by Dr. Amer, it could have been retrieved and prevented her from having the strut going to her heart and the subsequent surgery. ***Moore v. Singh*** is a subsequent surgery case, Your Honor. So we have met proximate cause. Proximate cause does not require a standard of care opinion. Dr. Sobieszczyk offered his opinions to a reasonable degree of medical certainty. That's exactly what happened in ***Moore v. Singh***. 03:46:21

Dr. Orcutt in that case did not offer a standard of care opinion. He simply said had the information been available, it could have been treated. So it's on all fours and we believe that there is evidence to go to the jury. 03:46:39

Moore v. Singh is also -- interestingly, Georgia is a directed verdict state. Directed verdict was granted and the Court of Appeals reversed it and said that the issue should go to the jury. Thank you. 03:47:00

THE COURT: All right. Thank you.

What is your comment on ***Moore***, Mr. Stoller?

MR. STOLLER: Your Honor, I've read the ***Moore*** case 03:47:17

and I disagree with plaintiff's characterization of it. What the *Moore* case stood for was two propositions. One was that there was no magic language required. But in overturning the directed verdict in that case, the Court noted that the plaintiff had provided expert testimony from multiple experts that, when taken together, met the standard of proof in that case but they articulated the standard of proof for causation particularly there as the following: Although plaintiff must introduce evidence which affords a reasonable basis for the conclusion that it's more likely than not the conduct of the defendant was a cause in the fact -- of the result, a mere possibility of such causation is not enough. 03:47:20 03:47:31 03:47:49

THE COURT: Let me ask you a question. We've read that language. As we learned in law school, the holding of the case is even more important than the language. Isn't it true that *Moore* held that an expert's testimony that a problem could have been solved was sufficient causation to go to the jury? 03:48:08

MR. STOLLER: What I would say, Your Honor, I've read *Moore* probably four times this morning to understand what happened in that case. And my read of that case is that they don't quote the testimony and they don't go where I think the defendants go. I think that the Court there, that the language of "could" is not where they hung their hat. 03:48:31

THE COURT: Is there any discussion of any expert testimony on causation other than could in the *Moore* case? 03:48:48

MR. STOLLER: In the *Moore* case they talk about -- and let me find the exact language, because they talk extensively in the *Moore* case about both Dr. Borkan and Dr. Orcutt and put that testimony together to say when you put -- and let me find their exact language because I do not want to misquote them. Here's the language. It immediately follows the quote I just read: Based on the combined expert testimony, we conclude -- based on the combined expert testimony, we conclude that *Moore* presented evidence creating a jury issue as to whether Dr. Singh would have discovered the fracture if she had properly complied with the standard of care during the examination of Rosemary during her hospitalization and, moreover, whether the fracture to diagnose -- I'm sorry, the failure to diagnose the fracture during that time led to further complications with the break such that the surgery was required to or made more complicated as a result of approximately two months of -- 03:48:56 03:49:08 03:49:30 03:49:46

THE COURT: Well, but that doesn't really respond to my question. My question is, can you see anywhere in that case where the Court refers to any expert testimony on causation other than the "could have" testimony that was given? 03:50:01

MR. STOLLER: Well, again, I think you have to look at everything they talked and they talk extensively about the opinions and testimony of the two experts and even as to Dr. Orcutt, one of the things they relied on was his opinion 03:50:18

testimony that the fracture was unlikely to have existed prior to the time at which the point in time at which they were looking at it. And from there on out, things exacerbated and became worse. There's not -- and that is in conjunction with the testimony from -- I've forgotten the first expert's name. I'm going to call him Dr. B just to be short and not look at it. But that Dr. B should have done something at that time specific to the break in place and taken action. 03:50:21 03:50:41

I distinguish it from this case in the following: I concede that they have evidence to go to a jury on the standard of care issue. 03:50:59

THE COURT: I know that point but you've left my question. I don't think there is any evidence cited in that case on causation other than could have. Can you point to any discussion of an expert's testimony on causation other than that? 03:51:15

MR. STOLLER: No. And my point is, Your Honor, I don't read that language as being the dispositive issue. I read that opinion as it being the combination -- because they don't point to one expert. If they thought could have was -- 03:51:29

THE COURT: They don't point to any causation evidence from the other expert; right?

MR. STOLLER: No. But what they say, Your Honor, is both. Both experts. They say the combined, which means that -- 03:51:42

THE COURT: It seems to me what you're asking me to do, Mr. Stoller, is to assume that there was more evidence in the combined opinions than could have. Isn't that what you're asking? 03:51:43

MR. STOLLER: What I'm asking you, Your Honor, to do is to read that case I think in the way it's fairly read, which is that it is not entirely clear what evidence was at issue and apply the principles which is you can't speculate. What we're left here -- so let me draw out of we're getting myopic in a case that does not lay out in particularity with what any of the expert says and says at the end of it based on the testimony, the combined testimony, the plaintiff met their burden there. And it's not clear what that combined testimony is. They don't point out -- when they come to their conclusion, they don't point it out and they don't explain it in detail what combination gets anybody there. 03:51:55 03:52:11 03:52:26

So I don't think we can rely on that -- I think getting myopic in it is a disservice to the general principles of law and the facts in this case because what they do say very clearly, both in that case and in ***Zwiren***, is you can't speculate. You cannot leave these issues to the jury to speculate and that is the case here. There is no testimony from anybody that anyone should have done anything and that if they had, that would have resulted in any additional act. 03:52:42

The chain of events we have to get to for them to 03:53:01

prove causation is standard of care was violated by Dr. Amer in not recognizing something in a filter that got blown up here but, in reality, was a much smaller part of a screen, that he then would have said, "Okay. I've recognized that that filter is fractured and somebody needs -- and I take that information to somebody else." I assume that's within the standard of care testimony. 03:53:04 03:53:21

But as part of the chain of causation, he now goes to Dr. B and says, "Dr. B, that filter appears to be fractured," and that Dr. B would then say, "Oh, I looked at that filter and now I think it needs to be removed." 03:53:35

There's nothing there that says that and the evidence is all over the place on what anybody would do under those circumstances. Again, their expert, who is supposed to put causation together, says, "I would have removed it." But he was very clear. I've made no statements or testimony about standard of care or negligence -- 03:53:51

THE COURT: He does say it could have been removed; right?

MR. STOLLER: Let me say this -- 03:54:04

THE COURT: Do you agree with that?

MR. STOLLER: Did he say it could have been removed? I don't recall.

THE COURT: He said it three times.

MR. STOLLER: Let me say this in response to that. 03:54:11

That is a meaningless statement. Of course it could be removed. It was ultimately removed. The filter -- there's no contention here the filter could not be removed. 03:54:12

THE COURT: Mr. Stoller, I'm understanding your argument. It seems to me it turns on whether or not I follow what appears to be the holding in *Moore* if, in fact, that evidence is an accurate description of what the expert said or whether I follow the broader language, which I agree is broader than what appears to be the holding, and I will read *Moore* again. 03:54:21 03:54:39

I understand your argument as to why if the broader -- well, I want to hear from Ms. Helm on this, but I don't think there's any evidence of would have from any expert. It's could have and the question is, is that going to be enough to go to the jury? 03:54:58

MR. STOLLER: Again, I'm going to step back to the general principle. We all know, practicing law without regard to a specific case, what we're asking the jury to do here on Dr. Amer is to speculate about what would have happened. Nobody has any idea what any doctor would have done under those circumstances. As distinct from -- and I'll distinguish this -- in the *Moore* case she had a broken leg. Nobody has to speculate to figure out if they identified she has a broken leg, they are going to cast it or do something. There's no clear -- that's something that is well within -- to use the 03:55:08 03:55:24

term they use in either ***Zwiren*** or ***Moore***, that's well within the ken of jurors to know she had a broken leg and somebody didn't find it. You need to do something whereas from here we've heard repeatedly from Bard witnesses, "It's okay to have these things in there. We leave them in." 03:55:27 03:55:41

THE COURT: I understand your point. Thank you.

Ms. Helm, briefly. Is there any other evidence other than could have in this case?

MS. HELM: No, Your Honor. Dr. Sobieszczyk testified could have. There are a couple issues that I think I need to address on ***Moore***. There's no discussion in ***Moore*** about speculation. In ***Moore*** there were two experts. There was Dr. Borkan and Dr. Orcutt. 03:55:53

THE COURT: I'm sorry to interrupt you. I'm going to read ***Moore*** again so I will read it carefully. What is, you think, wrong with Mr. Stoller's argument about ***Moore***? 03:56:08

MS. HELM: Because in ***Moore***, the testimony regarding proximate cause was could have and the holding is could have. It is not would have and the Georgia Court of Appeals said that was sufficient in it to go to the jury, so the holding in ***Moore*** is on all fours with this case and it's could have. 03:56:36

THE COURT: Okay. I understand that issue from both sides. I will read ***Moore*** again.

Second motion?

MS. LOURIE: Your Honor, the plaintiff moves for 03:56:55

directed verdict on the issue of intervening cause with respect to Dr. Kang and with respect to any of the radiologists that Dr. S spoke of earlier today. 03:56:57

Bard must prove by a preponderance of the evidence all three prongs set forth in the *Zaldivar* case which is a Georgia Supreme Court case of 2015. 03:57:11

The Court is well aware of the prongs, but I'll just mention the first two require that Bard prove that the action of the intervenor not be foreseeable by Bard, the second factor is that Bard cannot have triggered the action, and the third prong is that the action must be sufficient of itself to cause the injury. The *Zaldivar* case holds that all three prongs must be satisfied in order to have an intervening cause. 03:57:37

Your Honor, it is our position that it is clear and undisputed, as a matter of law, that Bard cannot prove prongs number one or number two. The evidence in the case shows that Bard knew that its filters were fracturing, including the G2, that pieces were traveling to people's hearts and thus it was foreseeable that a doctor would have to go into the heart to remove a piece of the filter. It's also foreseeable that in doing that, the doctor could cause harm to some part of the heart. 03:57:56 03:58:17

It's likewise foreseeable that if the filters were malfunctioning in a variety of ways, that radiologists might miss this on an incidental finding. 03:58:38

There's no evidence in the case that Bard can point to support a contention that either Dr. Kang's actions or these radiologists were unforeseeable. On the second prong in evaluating that, Bard cannot have triggered the action -- in our opinion, that's even stronger than the first prong. Bard manufactured the G2 filter. The filter fractured. As I said, a strut traveled to Ms. Booker's right ventricle and that is what triggered the action by Dr. Kang. It's also what triggered the actions of missing these reads by these radiologists if that is the contention. 03:58:41 03:59:04 03:59:28

On examination Dr. S was asked the question, can we agree that Dr. Kang would never have had to perform this percutaneous procedure had the filter not fractured?

And the answer was: That is correct.

That's clear evidence by their own expert that this is a result of something that they put into action, the chain of events. We just feel like there's no evidence in the case to submit any of this to the jury on intervening cause, that these prongs cannot be satisfied, and we ask that you rule as a matter of law. 03:59:47 04:00:11

THE COURT: Okay. Thank you.

MS. HELM: Your Honor, I think this argument falls into two pieces. The first piece being the intervening acts of the doctors prior to the strut being -- migrating to her heart. And as I understand Ms. Lourie's argument -- we agree that 04:00:35

there are three elements to the intervening cause and her argument is that Bard had an obligation to foresee that a doctor would commit malpractice. And the Georgia Supreme Court, in October of 2017, said for intervening cause, we don't have to prove that. We don't have to prove fault. That is the *Jordan* case decided in -- ***Jordan v. Everson*** that said for there to be an intervening cause, the intervening act does not have to be wrongful or negligent to break the causal chain. 04:00:40 04:01:00

So we did not have to prove that those other doctors other than Dr. Amer committed malpractice for them to fall into the first prong of the foreseeability. 04:01:21

We only had to show that it occurred. And there's no evidence that Bard foresaw that doctors would commit malpractice, the diagnostic radiologists would not properly read x-rays or report or CT scans and report it. Bard did not trigger the actions of these doctors. Bard had no responsibility for these doctors who were reading the films or -- and writing the reports that included the conditions that all of the experts in this case agree you can see in those reports. 04:01:43 04:02:04

So as to the treating doctors, prior to the strut migrating to the heart, it was not foreseeable to Bard that those doctors would not read -- accurately read the films and Bard did not trigger those doctors' actions. It had nothing to do with those doctors' actions. And, in fact, we all heard 04:02:21

that those films -- that would have been incidental findings and it wasn't related to the filter. 04:02:25

So as to the doctors prior to the strut migrating to her heart, there's no evidence that it was foreseeable to Bard. That's a question that should go to the jury and there's no evidence that Bard triggered the actions. In fact, I think Dr. Cousin answered that question pretty clearly yesterday when he was asked: Did the radiologist and Bard have anything to do with each other? And the answer was no. 04:02:39

As to Dr. Kang, there's a question to go to the jury of whether it was foreseeable based on all of the testimony that as to whether Dr. Kang should have gone through her heart. There's no question that it was not the filter that tore her tricuspid valve but it was the actions of Dr. Kang and there's no evidence that it was foreseeable to Bard that Dr. Kang was, in his language, going to make multiple attempts to go through the tricuspid valve and then tear that valve. 04:02:58 04:03:23

Bard did not trigger his decision to go through the tricuspid valve multiple times undirected as he testified and tear that valve. That action, in and of itself, is a cause of her injuries. So Bard has a established -- and there's question of fact as to all three elements as to Dr. Kang as well as to the other doctors. 04:03:43

THE COURT: Well, let me ask you a question. On Dr. Kang, I think the evidence is clear that if the filter had 04:04:05

not fractured, Dr. Kang never would have attempted to go into the heart. 04:04:12

MS. HELM: I think that's fair.

THE COURT: Do you agree with that?

MS. HELM: I think that's fair. 04:04:22

THE COURT: Which means that he went into the heart because the filter fractured?

MS. HELM: Right. Correct.

THE COURT: Doesn't that mean that the fracture triggered his action to go into the heart? 04:04:29

MS. HELM: No, Your Honor. Because he made -- what triggered his decision to go to the heart was a choice that he and Dr. Harvey made. We've heard evidence, and the jury can conclude from the evidence from Dr. Sobieszczyk, that that wasn't necessary. That didn't have to happen. So I believe 04:04:45 there's at least a question of fact for this jury to consider as to whether Dr. Kang should have gone into the heart in the first place.

THE COURT: It sounds as though what you're arguing is that conduct that is within the standard of care by Dr. Kang 04:05:01 to retrieve a strut from the heart was not triggered by the fracture of the Bard filter that went to the a heart.

MS. HELM: Your Honor, I think there's a step in that analysis that you left out. I don't dispute, no one disputes that the strut went to Ms. Booker's heart. Conduct that does 04:05:30

not have to be a violation of the standard of care can break the causal chain. That conduct was of the decision -- there's a question of fact as to whether the decision to go into the heart should have occurred or not. Dr. Kang made the choice. Dr. Sobieszczyk testified that he didn't need to do it. 04:05:37 04:05:51

THE COURT: But he didn't say it was below the standard of care.

MS. HELM: But, Your Honor, that's not the standard under Georgia law.

THE COURT: But I'm not focusing on the standard. I'm focusing on the trigger. And my point is, if a filter fractures and goes to the heart and going into the heart, to get it is within the standard of care, how can you say that going into the heart was not triggered by the fracture? 04:06:00

MS. HELM: Your Honor, going into the heart was a result of the fracture. But you've changed the standard under Georgia law. You say within the standard of care. For intervening cause we don't have to establish that it was a violation of the standard of care for it to be a break in the causal chain. 04:06:19 04:06:40

THE COURT: Well, but the problem I have with your argument is you're saying that the fracture did not trigger Dr. Kang's going into the heart because a different doctor might have chosen not to go into the heart.

MS. HELM: That, in and of itself, is a jury question 04:06:59

for the jury to decide, whether the fracture triggered it, whether he should or should not have done it, and whether the decision that does not have to be a violation of the standard of care under *Jordan* broke the causal chain. 04:07:01

THE COURT: Well, let me ask it differently. Is it wrong to say that a fracture which goes to the heart triggers whatever medical care would be appropriate after it goes to the heart? 04:07:14

MS. HELM: I think that's a -- yes.

THE COURT: And if Dr. Kang's medical care is appropriate, it's within the standard of care, it was triggered by the filter -- fracture going to the heart. 04:07:29

MS. HELM: But the standard is not whether it was within the standard of care. That is the difference. In Georgia it does not require that it be negligent or wrongdoing and I think -- respectfully, I think you're reading that into the standard. In October of 2017 the Georgia Supreme Court said for intervening cause -- and this is the conversation we kind of had in the charge conference. For intervening cause, it does not have to be a wrongdoing or a negligent act. So there's a question of fact here as to whether the torn tricuspid valve was triggered by the strut or it was triggered by the decision of Dr. Kang to go in there when there's a question of fact as to whether he should or should not have torn -- gone through the tricuspid valve. 04:07:45 04:08:08 04:08:29

THE COURT: Okay. I think I understand your argument. Before you leave, let me ask about the other doctors. 04:08:34

You in your argument mentioned malpractice a couple of times of the doctors who read the films. Are you asserting that there is evidence from which the jury can conclude that those doctors committed malpractice? 04:08:46

MS. HELM: No, Your Honor. We did not provide standard of care opinions as to those doctors. But, again, for intervening cause -- it's different than the non-party at fault statute that applies to Dr. Amer. We've made it very clear from the beginning we are not asking that these doctors go on the verdict form as non-parties at fault. 04:09:05

But for intervening cause, again, it does not require a showing of negligence which, in a medical case, would be a violation of the standard of care. 04:09:26

So the jury can consider their actions and consider that they were intervening causes without making the finding of violation of the standard of care or negligence.

THE COURT: Okay. I understand the position. Thank you. 04:09:49

Mr. Stoller, isn't everything you argued on cause applicable to step three of the intervening cause criteria as well?

MR. STOLLER: I'm sorry, Your Honor? 04:10:02

THE COURT: Well, for intervening cause, the intervenors' actions must have been sufficient to cause so the same argument you made with respect to Dr. Amer I assume you would make with respect to step three of the intervening cause. 04:10:04

MR. STOLLER: I think that applies to these other -- I've forgotten what they called them, missed opportunities and the other folks who allegedly didn't somehow step in and intervene. I think it's a little bit different there because at least with Dr. Amer, the standard is higher on the intervening cause issue which is that they have to prove that it was not foreseeable by Bard and Bard did not trigger the actions which is I think -- 04:10:18 04:10:35

THE COURT: I don't want to talk about that. My specific question is, on the third element, I'm going to let Ms. Lourie address those first, too. On the third element, is it your position that could have is not sufficient for the third element in intervening cause? 04:10:51

MR. STOLLER: I think that's correct, Your Honor. I think there's a whole host of reasons on those other ones but that is not -- they have the same problem with the intervening cause issues as they have with Dr. Amer. 04:11:05

THE COURT: Okay. I just wanted to make sure that I understood that.

Okay. Let me hear from Ms. Lourie on the rest of the issues. 04:11:16

MS. LOURIE: I just have a couple of additional comments. In the *Coleman* case, the Court held a negligent actor is liable not only for the injury caused by his own acts but is also liable for any additional harm caused from the manner in which reasonably required medical services are rendered. That is a restatement second of torts cite in that case. 04:11:19 04:11:44

We're not arguing that Bard has to show malpractice by Dr. Kang. We're arguing that Bard's action triggered Dr. Kang's going into the heart. And in the Court's instruction which cites the Georgia pattern I believe or -- I know we've messed around with it, but it also holds that even if Bard did not anticipate the details of the action and the injuries that it caused, it's still foreseeable. So I think the argument that they couldn't foresee that Dr. Kang would tear the valve and make the decision to go in, that is irrelevant once they trigger the cause of the need to go into the heart. 04:12:07 04:12:31

THE COURT: Okay. Thank you.

Ms. Helm, one more question. I may be mixing up cases that I read. But my memory of *Coleman* is that that's the cases where Doctor One committed malpractice. Doctor Two committed malpractice. The jury held that doctors one and two were both liable for the damages and the trial court let Doctor One off the hook by concluding that Doctor Two's malpractice or 04:12:49 04:13:31

an intervening cause and the Court held in *Coleman* that's wrong. Doctor One is responsible even if Doctor Two committed malpractice. Is that consistent with your understanding of *Coleman*? 04:13:36

MS. HELM: I think so, Your Honor. I don't have *Coleman* fresh but I think so. 04:13:56

THE COURT: I puzzled over that case because it seems to me what that would suggest here, somewhat inconsistent with the Georgia pattern jury instructions, that if the jury finds Bard negligent or liable for strict product liability, its responsible for Dr. Kang's actions even if he committed malpractice. 04:14:21

MS. HELM: I disagree, Your Honor.

THE COURT: Would you explain why?

MS. HELM: Yes, Your Honor. I think if you look at *Jordan*, which was decided last October, *Jordan* says that -- the Georgia Supreme Court says in *Jordan* that there can be an action, and it doesn't have to be malpractice, that can break the causal chain. 04:14:35

THE COURT: How is that consistent with *Coleman*? 04:14:53

MS. HELM: Well, Your Honor, I think --

THE COURT: Wouldn't Doctor Two's malpractice have broken the causal chain?

MS. HELM: I apologize, Your Honor, I can't speak to *Coleman* without having it in front of me. But I think *Jordan* 04:15:07

is obviously controlling because it was -- the Georgia Supreme Court was just decided in October. And, again, in the medical context there may be more foreseeability where here you're reading in that it was foreseeable to Bard that diagnostic radiologists would not report on what they saw in their films or, in the case of Dr. Kang, there's at least a question of fact that the jury has to decide whether he needed to go through and take the strut out percutaneously. 04:15:09 04:15:26

THE COURT: Okay. I'm going to take these two motions under advisement. I want to reread *Moore* and *Coleman* and *Jordan*. But I will get you a decision tonight on those. 04:15:43

I want to talk to you for a minute about the Dr. S issue that we talked about this morning. I went back, with the help of Jeff and looked at the motions *in limine*, the briefing on the motions *in limine*, the ruling that I made on the motion *in limine*. It's clear that the opinion by Dr. S about there being other intervening causes was identified in Bard's briefing and was argued in Bard's briefing and, in fact, portions of his opinion were quoted in the briefing which I had forgotten. And in the order that I entered, I said intervening cause can be asserted for Dr. Kang or others, I assume because of the way the briefing was written. I have no independent memory of why I said that when I drafted that sentence. But I think that's the reason. 04:16:52 04:17:20

The missed opportunity evidence was in his expert 04:17:40

report. He was listed as a trial witness. There was no motion *in limine* filed to keep that out. 04:17:43

So the question I have for plaintiff is: Do you believe there is a basis for me to exclude that evidence and if so, what's the basis if it was fully disclosed and in the report and not the subject of a motion *in limine*? What's the basis for keeping out the missed opportunity evidence from Dr. S if you have that position. That was I think an argument made this morning. 04:18:03

MR. O'CONNOR: We do have that position, Your Honor, and I think it's as we argued to you before, the way that evidence came out today, we objected timely on it. And the problem with it is this is: You know, what is a missed opportunity? And, secondly, now what's happening is the jury is left to speculate without guidance from any expert in this case about what a missed opportunity means for a Bard filter. In other words, what would have been done had that filter been addressed as they claim it should have been, reported as defense claims it should have been, and sent off to another doctor? That's the speculation and that is asking a lay juror to speculate on what would have happened. There has been no evidence that that filter was in a condition back at the dates that it was discovered, that somebody would have said under all circumstances, it needs to come out. 04:18:23 04:18:42 04:19:03

And if you think about it, the only way they would 04:19:21

get to that is if somehow the medical community was aware that a filter in a tilted position or with an arm pointed up, or whatever it is, is going to go on and fracture, migrate and go to somebody's heart. They have not linked anything up to the so-called missed opportunity. 04:19:23 04:19:41

THE COURT: Well, okay. I understand that. I think that is essentially the same argument that has been made. The causation proof isn't sufficient.

I thought that independent of that, you were asking me to exclude the evidence. I think you're asking me to rule in your favor on the issue because you don't think causation is sufficient. But it doesn't sound like you're asking me to exclude the evidence. 04:19:55

MR. O'CONNOR: But we are.

THE COURT: On what basis? 04:20:07

MR. O'CONNOR: On the basis that now it's in front of this jury and what do they do with it? They can only speculate about it.

THE COURT: But that's the motion you just made. If I rule in your favor, intervening cause goes out of the case. 04:20:18

MR. O'CONNOR: True.

THE COURT: But there's not an evidentiary basis for saying Dr. S couldn't testify to what he did testify to that I am hearing.

MR. O'CONNOR: Well, I think there is an evidentiary 04:20:33

basis and that he was speculating that when you talk about what could have happened, he's not saying that's what should have happened. 04:20:34

THE COURT: That's all he said. He said could have. He can express that opinion. The question you're raising is, is that enough? 04:20:45

MR. O'CONNOR: And what we're suggesting is absolutely not.

THE COURT: Okay. I understand that. Thank you.

Here's my question to the defendants: As things now stand and since I first proposed the jury instructions on Monday, the only instruction in the case about intervening cause is specific to Dr. Kang. It says nothing about others. The verdict form is specific to Dr. Kang. The defendants have said that instruction and verdict form are acceptable to you. Are you intending to argue in closing that there are other intervening causes? And if so, how should that happen without an instruction or a place in the verdict form to deal with that? 04:20:55 04:21:20

MS. HELM: May I approach the podium? 04:21:42

THE COURT: Please.

MS. HELM: First, Your Honor, I recognize the Court's frustration on this issue and I apologize. I missed this during the charge conference and in reviewing the charges, it was my oversight. We never intended to limit intervening cause 04:21:56

to Dr. Kang. As you've pointed out, we have raised it in expert reports. We argued it at length in motions *in limine* and we proposed jury charges. It was defendant's jury charge number six. 04:22:01

THE COURT: I went back and looked at them. I know they were not Kang-specific. 04:22:17

MS. HELM: Correct. They were not Kang-specific and as you've pointed out in docket 10055, we argued treating physicians.

THE COURT: I accept all of that. 04:22:31

MS. HELM: So my proposed solution, and I think I raised it this morning, is that the -- I believe that the jury charge on intervening cause can be revised to take out Dr. Kang's name specifically and refer to it as treating physicians and I have been playing with it a little bit today. 04:22:46 But that would be my proposal because the issue -- we believe the issue of intervening cause of more than one physician is properly before the jury.

THE COURT: Okay. All right.

MS. HELM: So, Your Honor, that was a long and -- 04:23:05

THE COURT: You think the verdict form and the jury instructions should be revised?

MS. HELM: Yes, Your Honor.

THE COURT: All right. Well, clearly what I need to do is rule on the question of whether intervening cause can go 04:23:16

to the jury on this evidence for both Dr. Kang and the other radiologists who read the films. If the answer to that is no, then we'll take out the intervening cause instruction and there will be no intervening cause defense. If the answer to that is yes, then I think all of that can properly go to the jury, we've clearly got to revise the instruction and the verdict form, which I will do. And we'll have to look at that in the morning when I get it to you if I come out that way. But I'm going to make my best effort tonight to get you my ruling on the issue of whether that defense is in the case as well as the comparative fault issue that has been argued. 04:23:21 04:23:36 04:23:54

All right. Are there other issues we need to address before we break?

MR. STOLLER: Two, Your Honor. I would like to address the verdict form issue and particularly on intervening cause. You added some words there. 04:24:12

THE COURT: Right. Go ahead.

MR. STOLLER: And we also need to -- we would like to address with you the FDA limiting instruction in light of additional information. 04:24:25

THE COURT: Go ahead.

MR. STOLLER: I'll approach the podium and, candidly, Your Honor, I think that what you just said and the defendants' position with respect to the other intervening acts makes even clearer why we should not have a line item on this verdict form 04:24:40

for intervening act and the jury allocating damages and I'll give you just as an example. 04:24:46

I think we talked earlier about that -- I think there's some -- this is ripe for confusion with if the jury comes and does everything we have instructed them to do and makes their proximate cause determination and finds liability, they are only going to award -- or they should only award in line B, those damages for which proximate cause has been proven. If there's an intervening cause, we fail on that. 04:24:58

But I'm trying to give an example of if they were to ignore that instruction and say -- and I'm just going to just use round numbers to keep things simple. They say we're going to ignore the proximate cause instruction and we'll find that there's a million dollars in damages based on the different elements and they fill in a million dollars in B, and then they go later, make their way down to C, and they decide yes and they decide okay, $300,000 of that is attributable to Dr. Kang. Just using this verdict form, that we would see a million dollars and 300,000 and we would say okay we need to subtract the 300,000 from the million and the award should be $700,000. 04:25:15 04:25:30 04:25:51

The problem is, that may happen but it is equally likely and, candidly, if they are doing what they are supposed to be doing with respect to determining whether there's an intervening cause and determining proximate cause in the first instance on the causes of action, it's equally likely, I submit 04:26:10

more likely, that what they do is they look at the various elements of the claim we're going to make, the various types of damages, and they are going to say they proved this one, we're going to give them this much. They proved this one, we're going to give them this much. They proved this one except, oh, Bard proved intervening cause on the tricuspid valve so we're not going to give them that one. 04:26:14 04:26:24

So what we end up with is they fill out the instruction and they say okay, $700,000 because, again, using my hypothetical, they have attributed $300,000 to the tricuspid valve, and then they go down to -- B or C, excuse me, and they check yes on number two and they are going to write 300 again. 04:26:40

THE COURT: That's why that parenthetical is in there.

MR. STOLLER: Your Honor, again, I submit I don't think that -- you're saying should not reduce the damages in part B by this amount. But they are not going to get there. They are not supposed to. The instruction and one of the first instructions even before we get to causes of action is the instruction on proximate cause. And what this instruction on intervening cause says is, if they prove intervening cause, we're not proving proximate cause. The instructions drive them to come up with a number that takes that out in the first instance and the arguments to the jury will be to take that out. You're not going to put that on this line. 04:26:54 04:27:07 04:27:28

And this problem gets compounded, quite frankly, if we now have, two, did they prove -- and I don't know who the missed opportunity doctors are, Your Honor, because I just don't, but they said there were at least two of them along the way. So now under superseding cause we have to add a three. If you found them liable is a missed opportunity, one, an intervening cause and now we have to have a line for that one and now we've got -- the question four or five, if missed opportunity two is an intervening cause, now a line for that one. And, candidly, Your Honor, the problem with those is, at least as I understood what Dr. S said, those intervening causes all lead to the same damage. So missed opportunity one was somebody -- there's a filter -- I'm sorry, there's an image of a filter somewhere along the way. 04:27:30 04:27:44 04:28:03

THE COURT: I understand that. 04:28:21

MR. STOLLER: Everything flows from that anyway so now we're going to have all of these numbers. Your Honor, again, plaintiff's position is C needs to come out.

THE COURT: We can just take out C and we would never know if the jury -- well, we would never know what the jury found on proximate cause or on intervening cause. 04:28:32

MR. STOLLER: I said we won't know what the jury found on proximate cause.

THE COURT: If we take out C, we'll never know what they found. And they come up with zero, we won't know if they 04:28:50

did that on the basis of intervening cause. If they come up with a number, we won't know if that was reduced by intervening cause or not; right? 04:28:54

MR. STOLLER: That's correct. We won't know whether they had found it to reduce it or not unless they will award us the full amount of our damages in which case we'll know that they didn't. 04:29:04

THE COURT: Well, maybe they would have awarded more if they hadn't taken into account --

MR. STOLLER: That's also true. 04:29:17

THE COURT: Okay. I understand that.

MR. STOLLER: I'm always happy to have them award more than we asked for.

THE COURT: Okay. Thank you.

MS. HELM: Your Honor, our issue is also with the superseding cause. We actually believe that there's a missing question and I understand the Court's preference not to have interrogatories. 04:29:30

THE COURT: Go ahead. I'm trying not to smile. One wants it out. One wants another question. What a surprise. 04:29:46

MS. HELM: I know, Your Honor. Two ships passing in the night.

The way that the verdict form is right now, we believe it should say: If you found Bard liable on any of the claims set forth above, do you find by a preponderance of the 04:29:59

evidence that the intervening acts of Dr. Kang or the treating physicians constituted a superseding cause? And if you find that, then you keep going. It just seems like it's a little bit confusing right now. So that would be our suggestion on the -- on that issue in the verdict form. 04:30:02 04:30:19

THE COURT: Okay.

501 -- or 510(k), do you want to make that argument?

MS. REED ZAIC: I'll be brief, Your Honor. We would like to renew our request for what we submitted as titled an FDA limiting instruction based on testimony that came in today. 04:30:39 In the Court's order at docket 9881 at page seven, it states that in denying plaintiff's motion *in limine* number one, any potential confusion can be cured if necessary by a limiting instruction regarding the nature of the 510(k) process.

I understand the Court's ruling on that issue and we placed objections on the record today although it might have been yesterday. Testimony came in today when Mr. Modra testified that was elicited by counsel that FDA never sent a warning letter to Bard about the design of the device. And I believe this creates a potential confusion to the jury that 04:31:02 04:31:20 this device was being reviewed for the safety of its design as if it were being reviewed for safety and efficacy by the FDA.

One additional point. There was previous testimony in the case that I think now may become more confusing because of a document that was entered into evidence today. Trial 04:31:39

exhibit 5483. At the top it says PMA related, and I understand Mr. Modra's explanation for why those words were there. However, in Dr. Tillman's testimony elicited by counsel, she said that principles of safety and effectiveness underlie the substantial equivalence determination and every 510(k) review in the same breath as when she was talking about the PMA process and the approval and it's a review process for safety. And this in conjunction with the document could lead to potential confusion. 04:31:42 04:32:00

THE COURT: So it's the proposed language that you're asking for? 04:32:15

MS. REED ZAIC: Yes, Your Honor, or a variation thereof depending on the argument that I've made.

THE COURT: Okay. Response?

MR. NORTH: Your Honor, I think the Court made a comment earlier today that -- or maybe it was last night that there did not appear to be any confusion in the testimony. I think we have been very careful to accurately portray the FDA process. I think it's apples and oranges to say that Mr. Modra was somehow implying that there was a finding of safety defectiveness of the device merely because he testified to a point that is absolutely true, that the FDA warning letter itself did not make any citation concerning the design of the G2. He didn't say that the FDA found the device safe and effective. He just said the undisputable fact that that 04:32:28 04:32:45 04:33:08

warning letter did not criticize the design. 04:33:12

THE COURT: Well, it was a little broader than that. The question you asked was whether Bard, to his knowledge, ever received a warning letter from the FDA about the G2's design.

MR. NORTH: Well, Your Honor, I think that's a 04:33:24
historical fact. I mean, Bard has never received a warning letter regarding the design of the G2. It is our position that this warning letter really is not relevant to the claims in Ms. Booker's case and we think we ought to be permitted to
establish that they don't have a warning letter that goes to 04:33:42
the design of the device or the warnings associated with the device. And that's all we established as a historical fact.

He said that and he said they never suggested a recall. He never once said they found it safe and effective. He's never once mistakenly said "approved" as opposed to 04:34:04
"cleared." He did not misrepresent the 510(k) process in the least. He merely cited historical fact on what the FDA has done and has not done through its regulatory enforcement powers.

The other testimony she cited was Donna-Bea Tillman, 04:34:21
who was actually quoting a guidance document when she said that, the very same guidance document that I think this Court has cited before on the order on the *Cisson* motion and perhaps in the preemption motion. While this Court has found that the
510(k) process does not involve an affirmative finding of 04:34:43

safety and effectiveness, the Court has acknowledged what the FDA guidance document says, that principles of safety and effectiveness underlie the 510(k) comparative process, and she was just quoting from that document. So we don't believe the instruction is necessary based on the record in this case. 04:34:46 04:35:00

THE COURT: Okay. I understand the parties' position on this.

Any other issues either side needs to raise?

MR. LOPEZ: I don't, Your Honor. I think Mr. O'Connor has a two-headed coin because I keep losing this one to have to talk to you about more time. I think we have 50 minutes left, Your Honor. I know we're ahead of schedule. We talked about it at sidebar. 04:35:13

THE COURT: You have 51 minutes.

MR. LOPEZ: You know, look, we've come a long way in this case and I understand we've had some issues with respect to our time. I hope Your Honor saw that we really worked hard on the defense part of this case to be as streamlined as possible. We know we took more time than we probably intended today because of the warning letter. As you know, that just got into evidence I think -- was it just yesterday; right? 04:35:31 04:35:49

And, again, I mean, we're at a point now where we're about to argue the first bellwether case and I think because we are ahead of schedule, we're still behind where I thought we might have been had we gotten the time that we thought we 04:36:10

originally would have, so we're asking you to have at least -- for us to have at least equal time to the defense. Tomorrow I think we both indicated an hour and 15 minutes. 04:36:13

Now, for the punitive phase, I understand that the testimony that needs to come in is about 18 minutes; is that right, Paul? The financial. 04:36:26

If we could have 15 minutes to argue once that is shown, which is not a lot of time to argue punitive damages. We're making that request to the Court in the interest of justice. Thank you. 04:36:44

THE COURT: All right.

MR. NORTH: Your Honor, I recognize this is totally up to the Court's discretion. I just note, though, that I believe that the defendants continue to be prejudiced by playing by the rules. 04:36:57

THE COURT: All right.

You can have an hour and 15 minutes for your closing total and you can have 35 minutes for your punitives case which should be enough for 15 minutes of argument plus your evidence.

Okay. We will plan to see you. 04:37:19

MR. LOPEZ: Thank you, Your Honor.

THE COURT: Is there another issue?

MS. REED ZAIC: This is -- my gesture wasn't recorded on the record because not knowing the answer to what day evidence was admitted. I can't remember what I said five 04:37:33

minutes ago at the podium. If the Court is inclined not to include our limiting instruction, I would like to supplement the objection we made earlier with the argument I stated. 04:37:35

THE COURT: I'm sorry. I didn't understand that.

MS. REED ZAIC: If the Court is not inclined to give us the limiting instruction that we've made a renewed request for, I would like to supplement the objection I made earlier on the record with the argument I just made at the podium. We objected today or yesterday about these and I just want to supplement with the argument I made. 04:37:47 04:38:03

THE COURT: I guess -- you want to make that argument?

MR. LOPEZ: No. No. I'm saying I've made the argument. But we did -- you asked us either today -- I think it was at lunch actually if we had objections that we wanted to place on the record with regard to issues regarding the jury instructions. 04:38:14

THE COURT: So you're incorporated that?

MS. REED ZAIC: I would like to supplement that objection if you deny it, Your Honor. 04:38:22

THE COURT: Okay. That's fine.

All right. We'll see you tomorrow. Let's make it 8:45. 8:45.

MR. LOPEZ: Thank you, Your Honor.

(Whereupon, these proceedings recessed at 4:38 p.m.) 04:38:32

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 29th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP